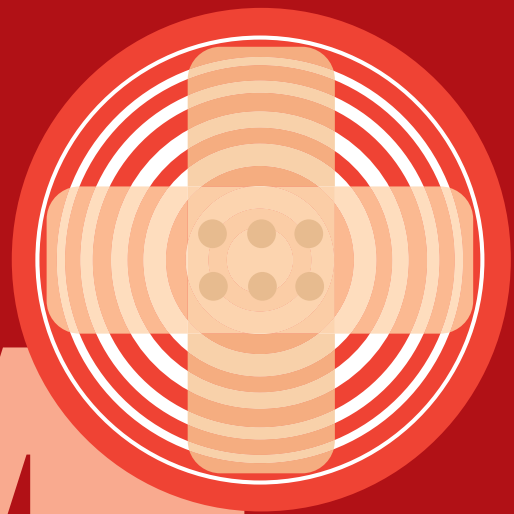


HOLISTIC MANAGEMENT OF WOUND-RELATED PAIN

AN OVERVIEW
OF THE EVIDENCE
AND
RECOMMENDATIONS
FOR CLINICAL
PRACTICE



Holistic management of wound-related pain:

an overview of the evidence and recommendations for clinical practice

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Abbreviations

| | | | |
|--------|---|---------|---|
| AV | Atrioventricular | PU | Pressure ulcer |
| BDI | Beck Depression Inventory | PUPP | Pressure Ulcer Prevention Programme |
| BPI | Brief Pain Inventory | QoL | Quality of life |
| BPS | British Pain Society | RCT | Randomised controlled trial |
| CALF | Conditioning activities for lower leg function | RSQ | Relationship Scales Questionnaire |
| CVI | Chronic venous insufficiency | SAS | Shortened Anxiety Scale |
| CVLU | Chronic venous leg ulcers | SIC | Used in brackets after a copied or quoted word that appears odd or erroneous to show that the word is quoted exactly as it stands in the original |
| DFU | Diabetic foot ulcer | SF-MPQ | A short form of the McGill Pain Questionnaire |
| DN4 | Douleur Neuropathique 4 Questions | TCM | Traditional Chinese medicine |
| ESEP | Extensive supervised exercise programme | TLQ-CVI | Tübingen Questionnaire for measuring quality of life in patients with CVI |
| ESWT | Extracorporeal shock wave therapy | TSAS-W | Toronto Symptom Assessment System for Wounds |
| EtD | Evidence to decision | UAD | Ultrasound-assisted debridement |
| EWMA | The European Wound Management Association | VAS | Visual Analogue Scale |
| FAI | Frenchay Activities Index | VLU | Venous leg ulcer |
| FLACC | Face Legs, Activity, Cry and Consolability scale | VLU-QoL | Venous leg ulcer quality of life |
| FRS | Faces Rating Scale | VRS | Verbal rating scale |
| GP | General practitioner | WAP | Wireless Application Protocol model |
| HADS | Hospital Anxiety and Depression Scale | WHO | The World Health Organization |
| HRQoL | Health-related quality of life | | |
| IASP | The International Association for the Study of Pain | | |
| LANSS | Leeds Assessment of Neuropathic Symptoms and Signs Scale | | |
| LLCM | Lindsay Leg Club Model | | |
| LLLT | Low-level laser technology | | |
| LFU | Low-frequency ultrasound | | |
| L OVE | Living overview of evidence | | |
| MECALF | Motivational enhancement and conditioning activity for leg function | | |
| MFW | Malignant fungating wounds | | |
| MPQ | McGill Pain Questionnaire | | |
| MV | Microvascular ulcers | | |
| NPRS | Numerical Pain Rating Scale | | |
| NHP | Nottingham Health Profile | | |
| NRS | Numeric Rating Scale | | |
| NWPT | Negative pressure wound therapy | | |
| PAINAD | Pain assessment in advanced dementia | | |
| PRISMA | Preferred Reporting Items for Systematic Reviews and Meta-Analyses | | |

Abstract

Background Pain is a significant factor associated with wounds. Its presence can impact on every aspect of an individual, affecting their overall quality of life (QoL) including ability to function, as well as their social and psychological well-being. Holistic approaches that can help to address wound-related pain are vital to improve patient outcomes.

Aim We aimed to review the evidence for the holistic management of wound-related pain in individuals with chronic wounds in order to provide recommendations for healthcare professionals in clinical practice.

Method The L OVE platform was used for the search as *wound* and *burn* are in the same search category. L OVE collects systematic reviews retrieved from the systematic reviews database Epistemonikos and allocates them to specific L OVEs and questions. We conducted our search for reviews related to wounds and burns in November 2022. Retrieved titles and abstracts were exported into Rayyan. The search was organised within Rayyan according to the focus for each chapter to retrieve evidence on pain assessment, physical therapies, patient education, psychological approaches, and complementary and alternative approaches. A systematic approach was used by senior experts in wound and pain management for double-blind screening and application of inclusion criteria (chronic wounds and pain) to agree on articles for review. Sources related to acute wounds (including burn injuries) were excluded. The L OVE search was supplemented by narrative reviews of literature identified from the individual systematic reviews and handsearching of relevant sources.

Results Thirty-eight systematic reviews and 27 additional articles were identified providing a total of 65 individual pieces of evidence. The number of reviews and articles included: pain assessment (n=25); physical therapies (n=8); patient education (n=12); psychological approaches (n=2); complementary and alternative approaches (n=18). The literature related to pain assessment highlighted that assessment of wound-related pain is complex and multidimensional. Healthcare providers must determine the most suitable assessment tool for their patients and

in doing so consider an individual's ability to respond to the assessment, as there is no one assessment tool to measure pain, as 'one size does not fit all'.

In terms of physical therapies, physical exercise is important, although the majority of evidence relates to individuals with venous leg ulcers (VLUs). In relation to management, clinicians need to recognize procedural-related pain, particularly in relation to debridement procedures. There may be a role for topical impregnated dressings and topical anaesthetics in this case. Equally it is important to manage moisture to prevent maceration and reduce the risk of pain from periwound skin irritation (dermatitis). For individuals with malignant fungating wounds (MFW) a combination of therapies to manage symptoms is recommended.

Specific research related to patient education and wound-related pain is lacking, however areas that should be considered include aetiology of the wound and causes of pain, non-pharmacological and pharmacological methods for pain relief, methods for assessing pain relief, as well as impact of pain on QoL. Psychological approaches need to consider the factors associated with pain (attention, cognitions, emotions and emotion regulation and overt behaviour) in order to determine the most appropriate treatment strategy. Evidence to make recommendations for wound-related pain is sparse; however, there may be a role for social models of care and motivation enhancement programmes for individuals with leg ulcers. Additionally, aromatherapy and music therapy may also be helpful. Evidence for other chronic wounds is lacking. There is some evidence to support the role of honey for the management of wound-related pain, specifically the research indicates that the analgesic action may be related to its anti-inflammatory properties. Evidence for traditional Chinese medicine (TCM), plants, low-dose topical steroids and low level-laser therapy was very weak.

Conclusion The experience of wound-related pain is complex and needs to take into consideration the psychological and social factors that can impact on an individual's QoL to ensure a holistic approach. Equally

the assessment of wound-related pain is complex and multidimensional. Healthcare providers must determine the most suitable assessment tool for their patients and in doing so consider an individual's ability to respond to the assessment. Management of wound-related pain may require both non-pharmacological and pharmacological approaches and can include dressings and devices. A holistic strategy should also incorporate both education (patient and healthcare professional) and psychological approaches to improve patient outcomes.

Our review has identified a lack of scientific resources on wound-related pain management to make clear recommendations for effective strategies. What is needed are further prospective studies of patients with wound-related pain and different types of non-healing wounds. Such research should be cognisant that a phenomenon as complex as pain must also be examined comprehensively. The phenomenon of pain has a high degree of subjective perception and individuals have different coping strategies, and healthcare professionals need to be mindful of this. The main determinants of wound-related pain management cannot solely be based on the wound symptomatology and the process of care (healing), but also need to consider the individuality of the patient and their current needs.

1. Introduction

Pain is a multidimensional phenomenon that is predisposed by biological, psychological and social factors which influence how pain is experienced and how it should be managed.¹ Additionally, individuals learn the concept of pain through life experiences.^{2,3} Pain, particularly chronic/persistent pain can also have adverse effects on function and on social and psychological well-being, therefore effective pain management is vital. In a study by Gardner et al.⁴ the authors reported that wound care procedures cause moderate to severe pain in up to 74% of patients and almost half (36%) of the patients with open wounds experienced severe pain. In combination with chronic wounds pain can also have a significant impact on the quality of life (QoL) of individuals.⁵ In fact, pain has been reported as one of the most difficult aspects for individuals with wounds to deal with, as it can impair activity, sociality and sleep.⁶

A detailed description of the search strategy methodology for each chapter is provided as appendices to this document. We searched the L OVE platform, which collects systematic reviews retrieved from the systematic reviews database Epistemonikos⁷ and allocates them to specific L OVEs and questions.⁸ The chapters are organised according to the L OVE filters applied. The Chapter 2 examines the multidimensional nature of pain, beginning with acute (nociceptive) pain, and aspects of chronic pain as it relates to individuals with wounds. Chapter 3 explores the evidence related to pain assessment to establish which assessment tools are being used in research and clinical practice. Chapter 4 considers the range of physical therapies available for the management of wound-related pain and offers some guidance for healthcare professionals. In this chapter 'physical therapy' does not relate purely to the professional practice of a 'physical therapist', instead the term has been applied in the wider context and according to the L OVE filters. Hence the role of interventions to manage anticipatory and procedural pain as well as inflammation are discussed. Chapter 5 examines evidence related to patient education, including determinants of non-adherence, tailored treatment regimes,

the role of social models of care, motivation enhancement programmes and the importance of listening to individuals. Chapter 6 reviews the role of psychological approaches to the management of wound-related pain, building on evidence from Chapter 2. The final chapter presents an overview of the evidence related to complementary and alternative therapies, according to the L OVE database categorisation. In this chapter the role of honey is reviewed, as well as traditional Chinese medicine, plant therapies, low level laser therapy and interventions for MFWs.

Each chapter provides a summary of recommendations based on the evidence, as well as the author group's clinical experience and expertise to guide implementation into clinical practice. The document concludes with a discussion of the challenges healthcare professionals and individuals face and where we see the current gaps in the evidence base.

Our approach to developing this document has been to frame the subject matter within a biopsychosocial framework to support a holistic approach to the assessment and management of wound-related pain. We recognise that the prevention of pain is also important, therefore we have tried to identify strategies that should help to minimise pain. We have discussed the role of non-pharmacological and topical pharmacological techniques, however the use of first line analgesics to manage pain are outside the scope of the document which is intended for healthcare professionals who are not pain specialists.

Detailed information about pain assessment tools and summary tables of the evidence included can be found online in a separate Appendices document.

2. The multidimensional nature of pain

2.1 Definition of pain

The International Association for the Study of Pain (IASP) defines pain as:

*An unpleasant sensory and emotional experience associated with or resembling that associated with, actual or potential tissue damage.*⁹

This definition is used widely and is applicable to wound-related pain as it refers to actual or potential tissue damage, such as may be present with an impending pressure ulcer/pressure injury (PU). The inclusion of the sensory and emotional aspects of pain ensures that the multidimensional aspects are fundamental to effective pain management.

Additionally the IASP categorises pain as acute and chronic.¹⁰ Box 1 shows the current definition of acute pain and Box 2 shows the definition of chronic pain.

Box 1: Definition of acute pain

*Acute pain happens suddenly, starts out sharp or intense and serves as a warning sign of disease or threat to the body. It is caused by injury, surgery, illness, trauma, or painful medical procedures and generally lasts from a few minutes to less than 6 months. Acute pain usually disappears whenever the underlying cause is treated or healed.*¹⁰

Box 2: Definition of chronic pain

*The IASP definition of chronic pain is pain that persists for 3 months or more and that it can, 'persist despite successful management of the condition that initially caused it, or because the underlying medical condition cannot be treated successfully'.*¹⁰

The World Union of Wound Healing Societies¹¹ categorised wound pain in five categories (Table 1).

Table 1: World Union of Wound Healing Societies categories of wound pain, adapted from World Union of Wound Healing Societies (2004)¹¹

| Category | Description |
|--|--|
| Operative pain | Due to surgery. |
| Procedural pain | Result of a routine basic procedures e.g., wound dressing change, wound debridement. |
| Incident pain | or 'breakthrough' pain can occur at any time during day-to-day activities, e.g., mobilisation causing the dressing to slip down, coughing putting pressure on a wound, repositioning or turning. |
| Background pain | Felt at rest when no wound care procedures are taking place. <ul style="list-style-type: none"> • Continuous or intermittent. • Related to the underlying cause of the wound, local wound factors (infection or maceration) and other pathologies (diabetic neuropathy, peripheral vascular disease). • underlying due to other illness not related to the wound, e.g., cancer. |
| Psychosocial influences on pain | Age, gender, education, depression, environment (noise level, timing), previous pain history, values and beliefs, all influence a patient's experience of pain and ability to communicate their pain to clinicians. |

These categories can help to guide the healthcare professional on what may cause wound-related pain and therefore the selection of appropriate pain management strategies. To manage pain effectively, the healthcare professional requires an understanding of pain, based on the biopsychosocial model, as this can help to explain

* We have included both terms here as the UK and other countries are still using the term pressure ulcer.

how and why an individual feels pain and where analgesic strategies work.

2.2 An introduction to the physiology of pain

Mechanisms associated with the experience of pain include nociceptive (tissue damage), inflammatory, neuropathic (nerve-related)¹² and ischaemic pain (which may be involved in incisional pain).^{10,13} Pain is a complex process, and to help understand it fully, it is important to firstly consider the nociceptive process (acute pain).

2.2.1 Acute pain

There are four physiological stages in nociception, which

Table 2: The anatomy and physiology of pain, adapted from Osterweis et al (1987) and Yam et al (2018)^{15,16}

| Normal pain processes | Definitions |
|-----------------------|---|
| Transduction | The process by which a painful physical or chemical stimulus is transformed into a signal that can be carried (via transmission) to the central nervous system. |
| Conduction | The phase where the action potential transmits the pain signal to the central processing center where depolarisation occurs at the presynaptic terminal. Interneurons will either transmit or inhibit the transmission through the dorsal horn of the spinal cord into specific lamina. |
| Transmission | The relay functions carry the message from the tissue injury site to the brain regions underlying perception. |
| Modulation | The neural process that acts specifically to reduce activity in the transmission system. |
| Perception | Subjective awareness is produced by sensory signals; it involves the integration of many sensory messages into a coherent and meaningful whole. It is a complex function of several processes, including attention, expectation, and interpretation. |

may give rise to the experience of pain: transduction, transmission, perception and modulation. They occur as a result of the transfer of stimuli from the site of injury in the periphery, via the central nervous system (spinal cord), through to the brain.¹⁴ The process is summarised in Table 2.^{15,16}

2.2.2 Transduction

Swift and Middleton¹⁴ summarised the physiology of pain. During transduction, following the peripheral stimulus, e.g., from tissue damage, wound management procedures or infection, the stimulus is changed into a nerve impulse (Figure 1). Nociceptors on the surface of the nerve endings respond to noxious stimuli and interact between the stimulus and the receptors. This triggers chemical changes through chemical mediators, including bradykinin, creating an action potential (electrical signal).¹⁶ Action potentials travel from the periphery to the dorsal horn in the 'conduction' phase. The larger the stimulus, e.g., tissue damage, size of the wound, the higher the frequency of action potentials, which may result in the individual experiencing more severe pain. The relationship between nociception and pain is non-linear and both are impacted by psychosocial factors.

Injury and inflammation lead to a cascade of activating factors from blood, local, migrating inflammatory cells and injured cells. They activate C fibres through receptors found on the afferent terminal that sensitise these terminals.¹⁸ Chemical mediators involved in the inflammatory process including substance P, prostaglandins and serotonin, are also involved in angiogenesis, vasodilation, cell growth and cell proliferation that occurs in wound healing.

Inflammation occurs as damage to the tissue releases inflammatory mediators causing arteriole dilation, and the area becomes discoloured/erythematous and hot. Contraction of the endothelium of capillaries and venules occurs with subsequent fluid and cell transmission into the local area causing swelling and pain.¹⁹

2.2.3 Transmission

There are three responses in the transmission phase, when the impulse travels to the brain (note that the impulses can travel up to and down from the brain), due to antidromic reflex or local neural peptide formation.²⁰

The impulses travel from:

1. Nociceptors to the spinal cord

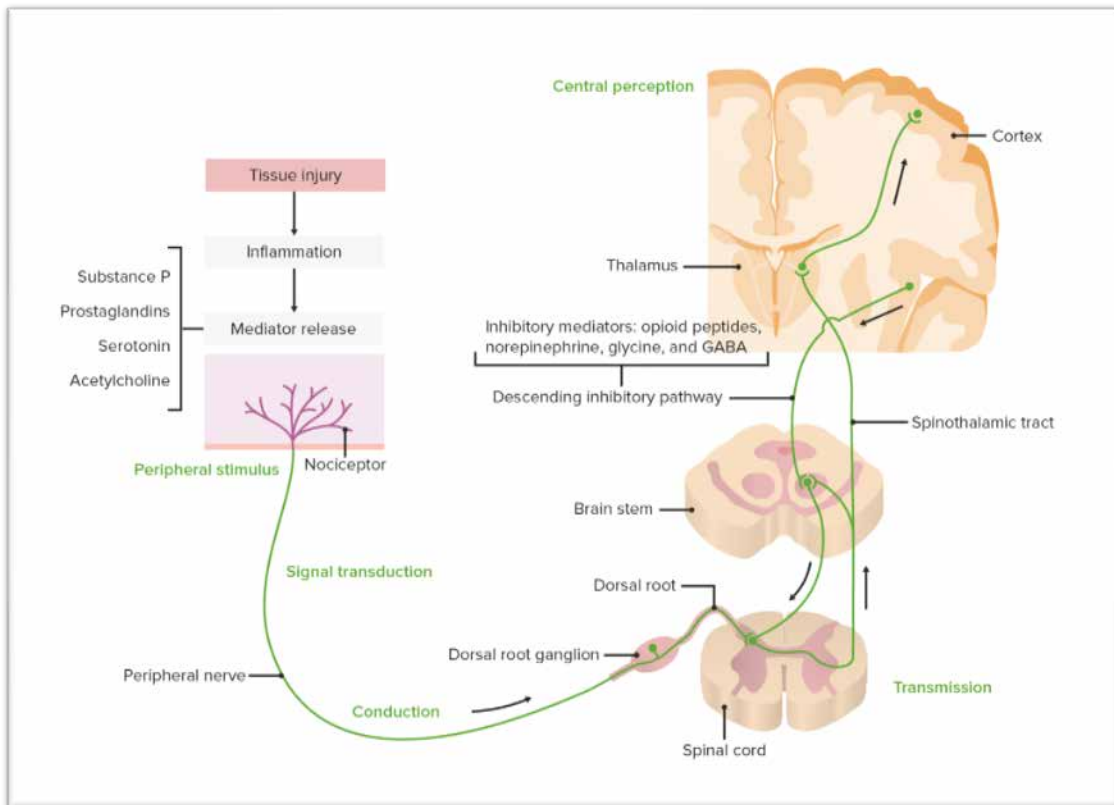


Figure 1: The basic route of nociception, transduction and transmission upon noxious stimuli in ascending and descending order. Lecturi Medical Education Resource (2022),¹⁷ permission to use granted.

2. Spinal cord to the brain.
3. Brain stem to other parts of the brain.

During the first response, impulse conduction occurs through the cycling of sodium and potassium channels between extracellular and intracellular fluid. This involves the A-delta and C fibres. The A-delta fibres are mildly myelinated, therefore they transmit impulses more quickly and produce the ‘first pain’ (sharp sensation) felt following injury. C fibres transmit more slowly and produce the ‘second pain’ (dull, burning sensation).

When the nociceptive impulse reaches the spinal cord, it crosses a synapse through the release of the neurotransmitters by diffusion, which activates a secondary neuron. Each neuron has a cell body in the dorsal root ganglion. It is a long process, an axon divides and sends one branch out to the periphery and one into the spinal cord. The primary afferent nociceptors have axons that are relatively thin and conduct impulses slowly. To release enough neurotransmitters to transmit the signal onto the next phase, sufficient activation of nociceptors is required

with facilitation and inhibition occurring within descending pathways.

2.2.4 Modulation

Modulation occurs through ascending and descending mechanisms. Ascending mechanisms, described by the Gate Control Theory of pain, are activated by touch or pressure. An example is knocking your hand and rubbing that area to reduce the pain felt. A-delta and C fibres trigger the secondary neurones. They then compete to transmit the secondary neurone, but if there is more activation of A-delta fibres (e.g., during rubbing), there is an alternative stimulus provided, creating descending inhibition, reducing the pain experience. During the descending mechanisms, from the brain down to the spinal cord, the descending nerve fibres release chemical mediators, endogenous opioids, gamma-aminobutyric acid (GABA), noradrenalin, neurotensin and serotonin. These inhibit the release of neurotransmitters, making it difficult for the secondary neuron to create a new action potential (the next phase).¹⁴

2.2.5 Perception

The individual experiences (feels) pain as a salient experience during the perception phase while recognising, defining, and responding to pain. This phase involves three areas of the brain, the cortex (location and motor response), the limbic system (emotional response) and the reticular system (arousal response). Distraction and relaxation techniques work in this phase to reduce the experience of pain.

Pain perception includes several psychological processes that provide feedback to influence pain perception. They are:

- Attentional orienting to the painful sensation and its source,
- Cognitive appraisal of the meaning of the sensation,
- Emotional, psychophysiological, and behavioural reactions.²¹

2.3 Chronic (persistent) pain

The definition of chronic pain was presented previously. The IASP further define chronic pain into two groups of chronic pain syndromes.²²

Chronic primary pain or chronic secondary pain²³: Chronic primary pain includes conditions such as fibromyalgia or non-specific low-back pain; Chronic secondary pain is secondary to another disease, surgery, or injury. Chronic pain in chronic wounds, may therefore be a type of chronic secondary pain. Chronic wounds may also have chronic secondary neuropathic pain.²⁴ Chronic pain often becomes the sole or predominant clinical problem in some individuals. Numerous physiological changes occur in the neuraxis as a result of chronic, persistent pain. These include neuropathic pain, wind up, sensitisation and neuroplasticity which are elaborated on in the following sections.

2.3.1 Neuropathic pain

Non-healing wounds result in an abnormal nociceptive pathway which can result in neuropathic pain and changes in sensation with peripheral and central changes due to nerve injury or peripheral neuropathy. The IASP define neuropathic pain as:

Pain initiated or caused by a primary lesion or dysfunction of the nervous system.^{25,22}

Neuropathic pain can be caused by damage anywhere along the neuraxis: peripheral nervous system, spinal or supraspinal

nervous system. It can also be caused by tissue and nerve injury, as well as by conditions such as diabetic neuropathy. It is characterised by the sensations described in Table 3. These painful sensations affect the individual's sensory system, their well-being, mood, focus and thinking. It is important to note that classic measures to reduce acute pain (nociceptive pain) are not effective for neuropathic pain as the neural pain transduction and transmission pathways are different.

Table 3: Peripheral and central changes due to nerve injury or peripheral neuropathy, adapted from Colloca et al (2017)²⁶

| Sensations | Descriptions |
|-------------------------------------|--|
| Dynamic mechanical allodynia | A type of mechanical allodynia that occurs when pain is elicited by lightly stroking the skin. |
| Expectancy-induced analgesia | A reduction of pain experience due to anticipation, desire and belief of hypoalgesia or analgesia. |
| Hyperalgesia | A heightened experience of pain caused by a noxious stimulus. |
| Hypoalgesia | A decreased perception of pain caused by a noxious stimulus. |
| Paradoxical heat sensation | An experienced sensation of heat provoked by a cold stimulus. |

Additionally, proprioceptors are sensory receptors that transduce itchy sensations and position sense, for example, of joints.

2.3.2 Wind up

Based on the Melzack and Wall theory of pain²⁷ the process of *wind up* was identified. Wind-up occurs when the pain signal into the central nervous system becomes stronger and longer lasting. This physiologic process involves activation of receptors normally dormant on post-synaptic nerve endings. Wind-up occurs anywhere in the spinal cord or brain (transmission, modulation and perception). When pain is persistent there is activation of receptors that are normally dormant on post-synaptic nerve endings. This is why pain starting in a small area progresses to a larger area, such as an injury to the finger that results in pain in the entire hand.²⁸

2.3.3 Sensitisation

As a result of prolonged high-frequency signalling into the dorsal horn, there is more stimulation of the transmitter glutamate (short-acting), substance P and Calcitonin Gene-related Peptide (CGRP), with consequent amplification of nociceptive information from the periphery into the central nervous system. When this state is achieved, neurones become sensitised. As a result, nociceptors become more efficient by three predominant mechanisms.²⁹

1. An increase baseline voltage across the cell membrane of the neurone
2. Production of more ion channels
3. Ion channels stay open longer

These processes contribute to a clinical phenomenon called central sensitisation.

During sensitisation, pain amplifies further due to the release of serotonin. In low quantities, serotonin can increase nociceptive signalling. In high quantities, there is an inhibitory effect. The brainstem can amplify nociception through high-frequency or prolonged nociceptive signalling.¹⁴

2.3.4 Neuroplasticity

Neuroplasticity is the ability of the brain and nervous system to adapt and change. Chronic pain can persist after damaged tissue(s) heals and can be due to nerve damage or a result of neuroplasticity secondary to the damage to tissues or neurons. The mechanisms involved in neuroplasticity occur throughout the neuraxis including the somatosensory circuit of the spinal dorsal horn, thalamus, and cortex associated with chronic pain.³⁰ Neuroplasticity in relation to pain is unhelpful as it can exacerbate persistent pain. Neuroplasticity can also become maladaptive; such as in persistent pain where protective systems become more efficient at doing their job, even when it is not required.

2.4 Pain and the wound healing physiological response

The normal physiology of wound healing occurs as a result of sequential overlapping phases to enable tissue reconstitution.³¹ Pain is often experienced during the inflammatory phase, when damaged cells, pathogens, and bacteria are removed from the wound area. Swelling, heat, pain and erythema occur because of the white blood cells, growth factors, nutrients and enzymes, and

it is associated with the peripheral phase of nociception. There is an increase in local biological mediators impacting nociception, either due to damage or from the inflammatory response itself.³² The build-up of fluid leads to swelling and the swollen tissues push against sensitive nerve endings. These and other chemical changes affect how nerves behave, which can contribute to pain.

In addition, there are intrinsic and extrinsic factors that affect wound healing for example, hypoxia, bacterial colonisation, ischaemia, reperfusion injury, altered cellular response, and collagen synthesis defects. Many of these will also stimulate the peripheral response in nociception and therefore need to be addressed as part of the assessment and management of pain.

2.5 Chronic wounds and chronic pain: what are the similarities?

Chronic, persistent wounds are characterised by full-thickness tissue loss in the form of arterial ulcers, diabetic foot ulcers (DFUs), venous ulcers, pressure injuries/ulcers, or infected open surgical wounds or from trauma. Chronicity in wounds is defined by the wound healing process itself and the subsequent non-response to treatment.^{27,33,34} They are described as a wound that does not heal within 4 weeks or, does not heal within an acceptable time of receiving standard care.³⁵ Ferreira et al³⁶ proposed a number of features of a chronic wound and argued that it should include at least one of the following:

- Persistent for more than three months
- Compromised vascularity or necrosis
- Presence of infection
- Associated comorbidities which impair the healing potential

The definition of chronic pain includes the feature of being present for more than three months; however, it does not include the notion of *persistent pain* which is more evident in the literature related to wounds. Therefore, it is important to approach wound care with the understanding that all wounds have the potential to be painful. The sources and triggers for wound-related pain (acute and chronic), are summarised in Table 4.

Table 4: Pain sources and triggers, adapted from Vuolo (2009)³⁷

| Type of pain | Type of source / trigger |
|------------------------------------|--|
| Tissue damage (nociceptive) | Initial wound trauma, e.g., burn, laceration, pressure damage Additional wound trauma, e.g., adhered dressings, abrasive cleansing, strong antiseptics Trauma to peri-wound skin, e.g., scratching, contact dermatitis from body fluid/chronic wound exudate, skin-stripping from dressing adhesives/tapes Inflammatory processes, e.g., infection, cellulitis, allergy, swelling, invasive procedures, e.g., biopsy, incision and drainage, sharp debridement (poor technique may result in injury to viable tissue). |
| Neuropathic (nerve related) | Exposed/dry nerve endings, e.g., leaving dressing off for prolonged periods Oedema causes pressure on nerves in the affected area Nerve stimulation, e.g., adhered dressings, wound swabbing, cold solutions Altered pain transmission, e.g., hyperalgesia, wind-up, allodynia Allergic reaction, e.g., itching, soreness Pathological pain e.g., neuropathy, ischaemia, arthritic External pressure e.g., compression bandaging, wound mapping, heavy bed clothes or tight clothing Thermal insult e.g., cold/hot cleansing solution Osmotic pressure e.g., honey, hydrocolloids Modalities, dressings or solutions which may sting or cause discomfort on contact e.g., some antimicrobials, topical negative pressure, larvae. |
| Emotional (psychological) | Anxiety/Stress/Fear Shame/Embarrassment Depression Wound symptoms e.g., malodour, high exudate levels. |

2.6 Psychosocial factors associated with pain

Many psychosocial factors contribute to the pain experience, including emotional (psychological) factors.³⁷ In individuals with chronic wounds and pain the clinician needs to be aware of these, as they will affect an individual's experience of chronic pain. Table 5 summarises the factors and potential consequences.

Table 5: Psychological factors in pain and their processes, adapted from Linton and Shaw (2011)²

| Factors | Descriptions | Possible effects on pain and disability |
|--|--|--|
| Attention | Pain demands our attention | Vigilance may increase pain intensity Distraction may decrease pain intensity |
| Cognitions | How we think about our pain may influence it | Interpretations and beliefs may increase pain and disability Catastrophising may increase pain Negative thoughts and beliefs may increase pain and disability Expectations may influence pain and disability Cognitive sets may reduce flexibility in dealing with pain and disability |
| Emotions and emotion regulation | Pain often generates negative feelings. These negative feelings may influence pain and fuel cognition, attention, and overt behaviours | Fear may increase avoidance behaviour and disability Anxiety may increase pain disability Depression may increase pain disability Distress, in general, fuels negative cognitions and pain disability Positive emotions might decrease pain |
| Overt behaviour | What we do to cope with our pain influences our perception | Avoidance behaviour may increase disability Unlimited activity (overactivity) may provoke pain Pain behaviours communicate pain |

The chapter on psychological approaches for wound-related pain management will return to these factors to suggest treatment strategies.

Pain perception is modulated by cognitive and emotional variables such as predictability, controllability, attentional focus, or fear of pain. The psychological factors that modulate the perception of pain include:

- Expectancy
- Perceived controllability
- Fear and anxiety
- Appraisal processes
- Perceived self-efficacy (an individual's confidence in their ability to control or manage various aspects of health conditions associated with pain, such as pain and disability), and
- Contingencies of reinforcement.^{38,39}

Increased stress levels, cortisol levels, and the thought of

pain can affect wound healing. Heightened anxiety lowers an individual's pain threshold and tolerance and may result in increased vigilance of somatic signals. This has the potential to impact neural sensitisation. The vicious cycle of pain, stress/anxiety and worsening of pain can delay wound healing.^{6,40}

2.7 Psychological factors that influence the experience of wound pain

Psychological factors that influence the experience of wound-related pain include the wound (non-healing, exudate, odour), fear and anxiety (non-healing, pain during wound care, background pain), poor sleep, traumatic experiences (previous/historical) and depression (a long-term condition or may be linked to the wound / persistent pain).^{6,40,41} In addition, individuals with chronic wounds

often have comorbidities which can influence wound healing and their experience of pain. A multidisciplinary approach to managing individuals is essential to provide appropriate person-centred care. The biopsychosocial Integrated Wound Pain Model provides a useful framework to help understand the complexities of wound-related pain (Figure 2).⁴²

2.8 Social factors that influence the experience of wound pain

Table 6 summarises the biopsychosocial factors associated with chronic pain. Social factors that influence the experience of wound-related pain include levels of education, social deprivation, isolation, poor/reduced mobility and culture.^{41,43}

INTEGRATED WOUND PAIN MODEL

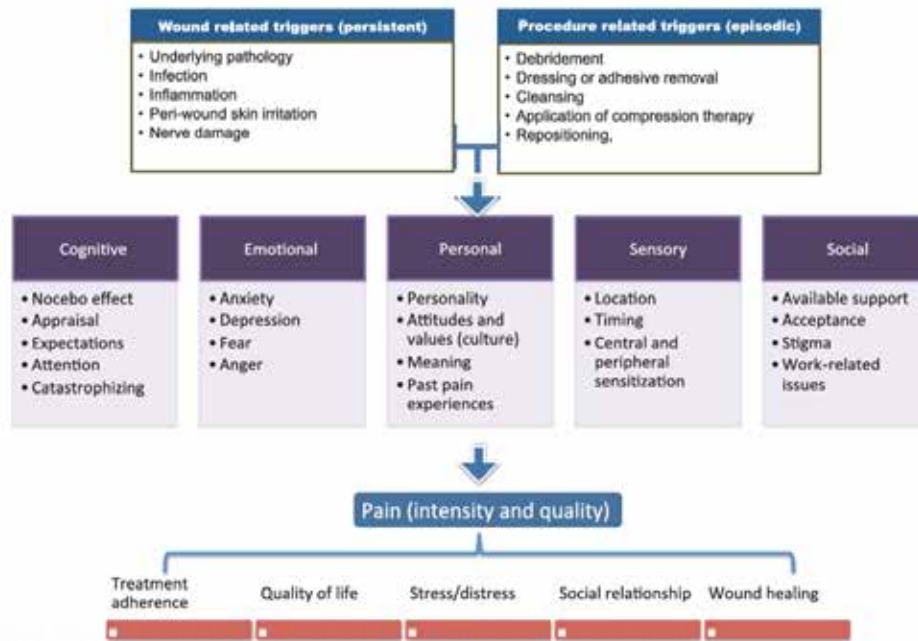


Figure 2: Integrated Wound Pain Model. Woo (2012),⁴² permission to use granted

Table 6: Biopsychosocial factors associated with the development of chronic pain, Mills et al (2019)⁴⁴, pe274

| Factors | | Factors | |
|-------------------------|---|----------|---|
| Demographic | Age | Clinical | Pain |
| | Gender | | Multi-morbidity and mortality |
| | Ethnicity and cultural background (social) | | Mental health (social and psychological) |
| | Socio-economic background (social) | | Surgical and medical interventions |
| | Employment status and occupational factors (social) | | Weight (physical and social) |
| Lifestyle and behaviour | Smoking (social) | | Sleep disorders |
| | Alcohol (social) | | Genetics |
| | Physical activity (social) | Other | Attitudes and beliefs about pain (social) |
| | Nutrition (social) | | History of violent injury, abuse of interpersonal violence (psychological and social) |
| | Sunshine and vitamin D (social) | | |

These factors should be taken into consideration in assessing individuals with wound-related pain. More recently perceptions of injustice⁴⁵, the influence of significant other^{46,47} and their beliefs are also important psychosocial factors from the chronic pain research.

In considering the impact that wound-related pain can have on the individual, it has been established that understanding the pain experience and how it should be managed is not just about pharmacological and non-pharmacological strategies. The experience of pain is subjective and complex and involves psychological and social factors that can impact on an individual's QoL. Figure 3 illustrates the consequence of these factors.⁴⁸

In relation to wound-related pain, management needs to be person-centred and should empower the individual to take control of their condition⁴⁹ with support from the wider multi-disciplinary team.

2.9 Wound-related pain and person-centred care

The European Wound Management Association (EWMA) published a document in 2020 examining the importance of person-centred care emphasising the need to include individuals as partners in their care and treatment. Of equal importance is ensuring that the needs of the individual are at the core of the decision-making process.⁵⁰

2.10 Key points regarding the nature of wound-related pain

- Wound care procedures have been shown to cause moderate to severe pain in 74% of individuals with open wounds.
- Pain impacts on activity, sociality, and sleep.
- The experience of pain can be related to tissue damage, nerve-related and ischaemic pain.

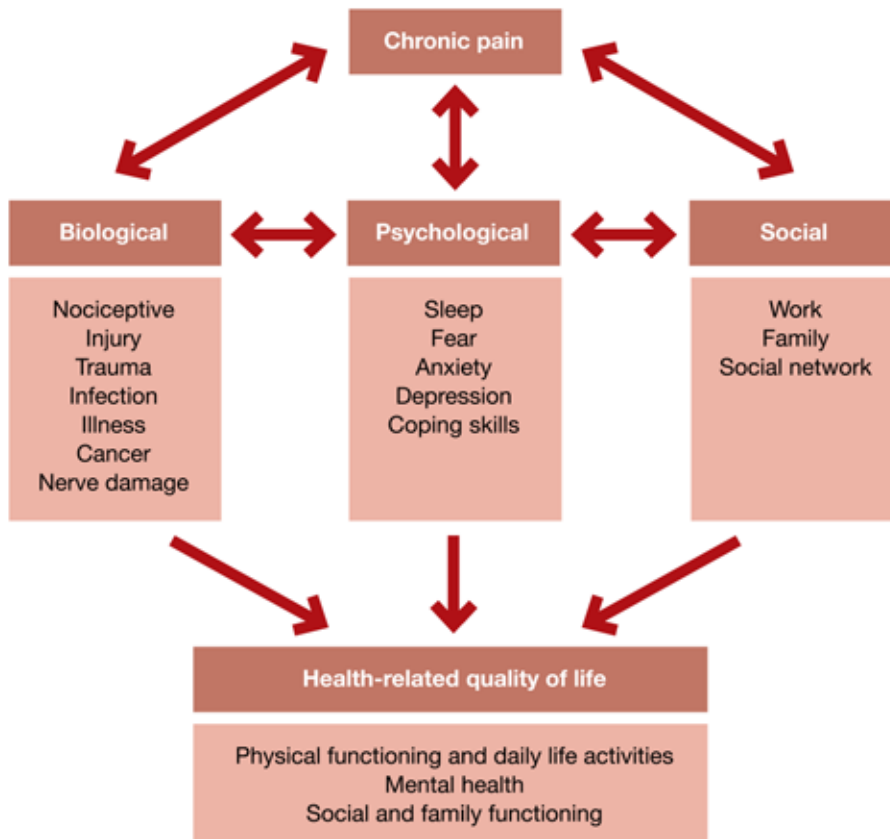


Figure 3: Biopsychosocial model of pain and consequences on the quality of life, adapted from Duenas et al (2016),^{48 p457}

- The presence of a non-healing wound can give rise to neuropathic pain due to maladaptive plasticity via complex neuro-immune-endocrine interactions.
- Pain is a normal sign in the inflammatory phase of wound healing, so all wounds have the potential to be painful. In combination with other intrinsic and extrinsic factors pain can be exacerbated. Therefore, there is a need to address these as part of the assessment and management of an individual with a wound.
- Psycho-social factors contribute to the pain experience, particularly emotional (psychological) factors which can also act as modulating factors.
- The experience of wound-related pain is complex and needs to take into consideration the psychological and social factors that can impact on an individual's QoL.

The next chapter will examine the topic of assessment of wound-related pain.

3. Wound-related pain assessment

3.1 Introduction

This chapter reviews evidence related to assessment tools for pain, specifically wound-related pain, and chronic wounds. For the review we supplemented the search for systematic reviews with an update of a previous scoping review undertaken for pain assessment in individuals with chronic lower leg wounds⁵¹ to present a narrative review of the evidence. The updated review sought to identify evidence for all chronic wounds of any aetiology. The search strategy and results identified using the L OVE platform are presented first, followed by the narrative review. A summary of recommendations from the evidence, clinical experience and expertise is provided at the end of the chapter to facilitate implementation into clinical practice.

3.2 Method

3.2.1 Search method

The search strategy aimed to find systematic reviews related to the wound pain assessment. We searched L OVE platform, which collects systematic reviews retrieved from the systematic reviews database Epistemonikos⁷ and allocates them to specific L OVEs and questions.⁸ We conducted a search in L OVE for *wounds* and *burns* on 4 November 2022, and retrieved relevant systematic reviews using this combination of keywords: *Pain* AND (*assess** OR *Measure** OR *evaluat** OR *apprais** OR *tool** OR *scale** OR *questionnaire** OR *test** OR *chart** OR *survey** OR *diary* OR *diaries* OR *report** OR *self-report** OR *intensity* OR *severit** OR *instrument** OR *NRS* OR *VAS* OR *VRS* OR *SF-MPQ* OR *MPQ* OR *WBFPS* OR *FPS*) There were no language, publication year or publication status restrictions.

We screened the reference lists of all eligible systematic reviews and hand-searched websites of relevant organisations/institutions and other sources.

3.2.2 Inclusion criteria

Systematic reviews of pain and chronic wounds which discussed an assessment of wound-related pain.

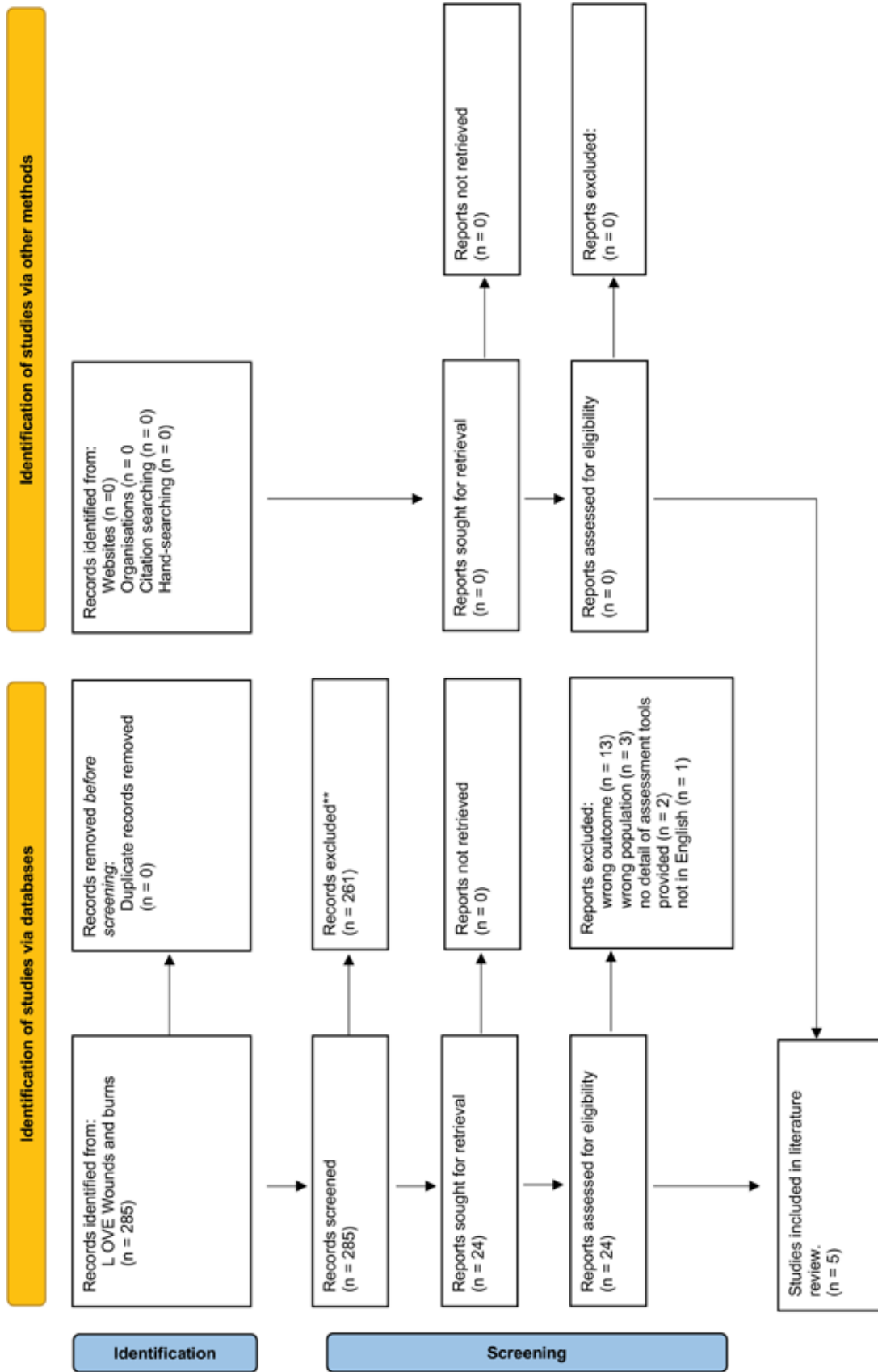
3.2.3 Exclusion criteria

Acute wounds, burns (burn injuries)

3.2.4 Selection of studies

Retrieved titles and abstracts were exported into Rayyan⁵² by an information specialist Simona Slezáková. The title and abstracts were screened in duplicate and independently by two authors, Nicoletta Frescos and Kirsti Ahmajärvi. The blind mode within Rayyan was kept on until both authors had completed the first screening. Subsequently, the blind mode was turned off to allow the authors to view each other's decisions. The authors then met to resolve the disagreements and agree which results would move to the second stage of a full-text review of selected articles. Full-text screening was conducted similarly to the title and abstract screening. Following the full-text screening a list of studies for inclusion/exclusion was created. The original search yielded 285 results. Following the title and abstract screening 261 were excluded, the main reason for exclusion being the wrong outcome or population. This generated 24 articles for full text review. Of these, 19 full texts were excluded as they did not have the relevant outcome, population, the detail of assessment tools used in the studies or were not written in English. Five reviews met the inclusion criteria and were included in the analysis. The screening and assessment process is described in detail in the flow diagram (Figure 4).

Figure 4: Flow diagram of the screening and the assessment process for wound related pain (modified PRISMA 2020 flow diagram)



3.2.5 Data extraction

Relevant data were extracted from the included reviews by Nicoletta Frescos and reviewed by Kirsti Ahmajärvi.

3.3 Results

3.3.1 Characteristics of the systematic reviews

The five systematic reviews identified a total of 144 studies. The number of studies included in each review ranged from 13 to 70 and the date range for the database search was from 1980–2022 across all the reviews. The studies included in the reviews were conducted predominantly in the United Kingdom, Sweden, Germany, United States with fewer in Portugal, Spain, Poland, Switzerland, Canada, France, Australia, New Zealand, China, Brazil India, Netherlands, Italy, France and Denmark. One study⁵³ did not provide information related to geographical location.

Three of the reviews^{53,54,55} focused on wound related pain in patients with chronic leg ulcers (venous, arterial and mixed wounds), one review investigated MFWs⁵⁶ and one investigated skin diseases which were predominately studies related to chronic ulcers (PUs, venous leg ulcers (VLUs) and arterial ulcers).⁵⁷

In their literature search on PUs/injuries and the treatment of pain, malodour and exudate, De Laat et al.⁵³ said the McGill Pain Questionnaire (MPQ), the Visual Analogue Scale (VAS) and the Faces Rating Scale (FRS) (Appendix 1) were useful tools in the assessment of pain in patients with PUs. The authors stated that although the MPQ has not been tested specifically in patients with PU, it provides a description of the qualities of pain and measurement of pain intensity. De Laat and colleagues noted that the MPQ was difficult for some patients to complete in particular for patients who were acutely ill. They suggested that the VAS was an easy and suitable tool to measure pain associated with PUs, as was the FRS which is known to be useful for patients with speech problems and cognitive impairment. In summary, De Laat and colleagues concluded that the MPQ, the VAS and the FRS are useful instruments to assess PU-related pain.⁵³

The VAS consists of a horizontal line of 10cm long, with ‘no pain’ at one end and ‘worst imaginable (or possible) pain’ at the other end (Figure 5a). Individuals are asked to mark the position on the line that best reflects the intensity of their pain.^{53,58} Subsequent iterations of the tool include numbers where 0 is no pain and 10 is the worst possible pain (Figure 5b).

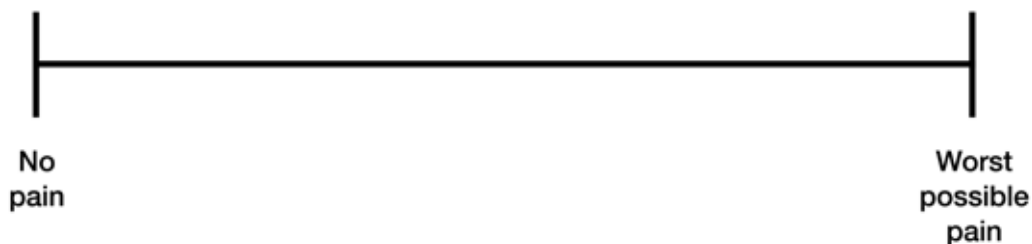


Figure 5a: Traditional Visual Analogue Scale (VAS), de Latt et al (2005)⁵³

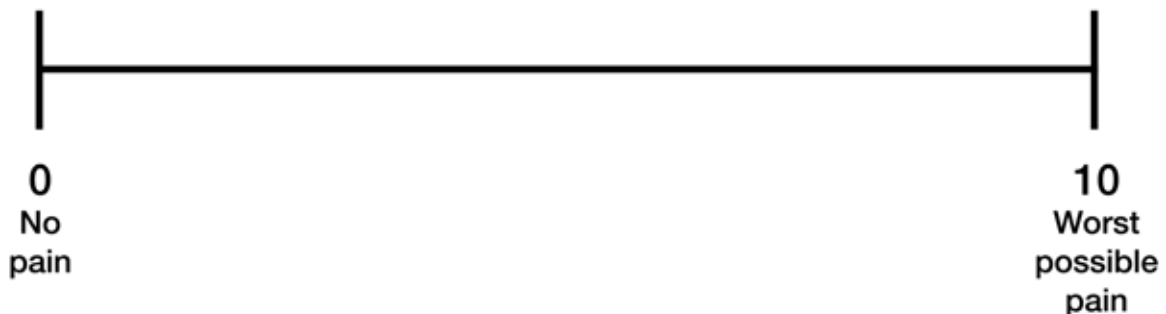


Figure 5b: Adapted Visual Analogue Scale (VAS), adapted from European Pain Federation⁵⁹

Note: A mark is placed on the line at the point that represents the level of pain observed. This is measured in millimeters from the left anchor “no pain” to generate a pain score. The word “distress” can replace “pain” to create a distress scale.

Herber et al.⁵⁴ undertook a systematic review to examine the impact of leg ulceration on patients' QoL. Twenty-four studies including quantitative, qualitative, and mixed methods were analysed. Pain was described in 11 quantitative and qualitative studies. Thirteen quantitative studies used various QoL and pain assessment instruments to analyse the impact of venous or arterial leg ulcers. The Herber and colleagues stated that overall the studies used validated assessment tools and the frequency of tools used were: Short-form McGill Pain Questionnaire (SF-MPQ) (n=4 studies), Nottingham Health Profile (NHP) (n=3 studies), Hospital Anxiety & Depression Scale (n=2 studies), Health Locus of Control (n=2 studies) (Appendix 1), Short-Form Health Survey (SF-36)⁶⁰ (n=2 studies), Life Satisfaction Index (n=2 studies), and the Numerical Pain Rating Scale (NPRS) (n=1 study) (Figure 6). One study from Germany used the Tübinger Questionnaire for measuring QoL in patients with chronic venous insufficiency (TLQ-CVI) and another study used the modified version of the Skindex, which is a generic instrument to measure of the effects of skin disease on QoL. It has been used as a basis for more specific tools to measure QoL in particular populations, such as the venous leg ulcer quality of life (VLU-QoL).⁶¹

There are various iterations of the Numeric Rating Scale (NRS) and verbal rating scale (VRS), including combinations of both i.e. Numerical Verbal Scale (NVS) or Verbal Numerical Rating Scale (VNRS) or Numeric Pain Scale (NPS). The most commonly used scale in research is the NPRS. In clinical practice the verbal scales are more widely used.

As reflected in the various QoL tools outlined in this study, pain is a multidimensional experience. QoL questionnaires can be classified into generic (e.g., SF-36), disease (e.g., VLU-QoL) and domain specific (e.g., MPQ). Wound related pain encompasses numerous domains including physiological, sensory affective and behavioural and accurate pain assessment can be influenced by a variety of

factors such as stress, anxiety and coping skills.⁶³ The choice of tool is dependent on what outcome measures are sought, as specific questionnaires do not necessarily capture the full impact of wound related pain on QoL but can be supplemented with an additional, relevant generic tool which can result in a more detailed understanding of the impact.

A more recent systematic review by Purcell et al.⁵⁵ examined the effectiveness of topical analgesics and topical local anaesthetics for reducing pain in chronic leg ulcers. The review included 23 studies the majority of which were in Europe (n=20). With regards to the assessment tools used to measure pain, these included the NRS (n=5), VAS (n=15), VRS (n=3), and numeric box scale (n=3). For the studies using topical anaesthetic agents the VAS was the predominant pain assessment tool used. The possible reason why the VAS was commonly used in these trials could be due to the ease of administration and scoring and its conceptual simplicity, which can be an advantage in terms of time efficiency for data collection. Furthermore, the VAS is the most studied and commonly used tool in clinical studies and is considered to be the gold standard for pain intensity measurements.⁶⁴

Gutierrez et al.⁵⁷ conducted a systematic review on the use of topical opioids for various skin diseases, including chronic ulcers, burns, oral lichen planus, post photodynamic therapy and split-thickness skin grafts. The review analysed common formulations of either topical morphine and diamorphine in combination with a hydrogel. Of the 14 studies reviewed, 9 studies focused on chronic wounds, (PUs (n=4), venous and/or arterial ulcers (n=3), or ulcers of various aetiologies (n=2) including traumatic, malignant, cellulitis, and necrotic angiodermatitis). The pain assessment tool used for PUs were VAS (n=2), NRS (n=1) and VRS (none, mild moderate, severe and overwhelming) (n=1). For venous and/or arterial ulcers two studies used

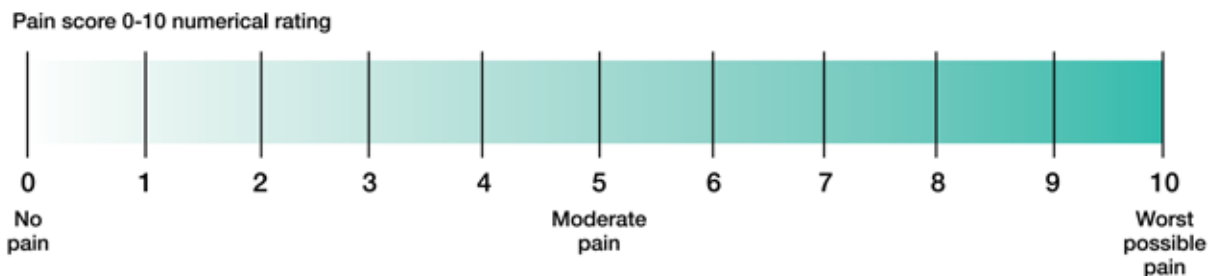


Figure 6: Numerical Pain Rating Scale, adapted from Physiopedia Pain (2023)⁶²

VAS and one used NRS. One study on traumatic wounds, malignant wounds and cellulitis used the NRS for their measurement of pain, the other referred to the use of a Numeric Pain Scale (NPS). On further review the NRS and the NPS were one and the same.

The use of three different unidimensional pain assessment tools were identified in these studies, which highlights a lack of consensus in the type of pain assessment tools used and questions the homogeneity and generalisability of pain outcome measures across different wound aetiologies.

Da Costa Ferreira et al.⁵⁶ conducted a scoping review to synthesise the literature on topical therapies for wound pain management in individuals with MFWs. Of the 70 studies reviewed, the authors found that for the majority of the studies, pain was not assessed using a validated tool. In fact, less than one-third (31.4%) of the studies assessed wound related pain using standardised assessment tools. The tools most commonly used in 22 studies were the VAS, the Numerical Verbal Scale and the multidimensional MPQ. One study assessed pain by categories (no pain, weak, moderate and severe).

3.4 Summary of the evidence from the systematic reviews

Based on the findings of the five systematic reviews evaluated there is evidence related to the assessment of pain in individuals with chronic wounds including, PUs, leg ulcers and MFWs (Appendix 2). In some studies pain was assessed using a form of rating scale i.e., VAS, NRS, McGill, FRS in other studies pain and discomfort was assessed as part of a wider consideration of QoL. Given the multidimensional nature of pain, it is perhaps justified to use more comprehensive measures that incorporate QoL and reflect a biopsychosocial approach to pain. However, we also recognise that there are circumstances where clinicians want to be able to assess wound-related pain specifically, therefore, as part of this chapter we also undertook a wider review of the existing evidence with a view to developing recommendations for clinical practice.

3.5 Narrative/thematic review of assessment of wound-related pain

3.5.1 Search strategy

We conducted a further literature search for validated pain assessment tools to assess and/or measure wound related pain. The search strategy aimed to find relevant

and high-quality literature related to the topic of *validated pain assessment tools to assess or measure wound related pain*. The following databases were searched on the 23 December 2022 in collaboration with a research librarian. Medline (Ovid Platform 1946 onwards), Embase (Ovid Platform 1947 onwards), PsycINFO (Ovid Platform 1806 onwards) and CINAHL (EBSCO Platform 1937). The literature search was limited to the following study types, clinical trials, guidelines, systematic review, meta-analyses, observational studies, validation studies or randomised controlled trials (RCTs). Search results were limited to English language and human articles only. Lower limb/ extremities-related articles were excluded. There were no limits or restrictions placed on publication years or publication status.

The following MeSH and keywords were searched using the appropriate Boolean operators: Pain Measurement/, "Surveys and Questionnaires"/, Nursing Assessment/, Pain/, Chronic Pain/, Nociceptive Pain/, Pain Perception/, "Wounds and Injuries"/, Wound Healing/, Ulcer/, Surveys/, exp Questionnaires/, exp Measurement/, (MH "Wounds and Injuries"), (MH "Wounds, Chronic"), (MH "Fungating Wounds"), (MH "Wounds, Penetrating"), (MH "Surgical Wound Dehiscence"), (MH "Pain"), (MH "Questionnaires"), (MH "Surveys"), (MH "McGill Pain Questionnaire"), (MH "Clinical Assessment Tools"), (MH "Pain Measurement"), (pain adj2 assessment*), (pain adj2 tool*), (pain adj2 score*), (pain adj2 questionnaire*), (pain adj2 survey*), (pain adj2 measure*), (pain adj2 scale*), (pain adj2 instrument*), (pain adj2 chart*), (pain adj2 appraisal*), (pain adj2 indicat*), (pain adj2 self report*), (pain adj2 check list*), pain*, pain assessment tool*, pain scale*, pain measure*, pain assessment*, pain rating scale*, pain questionnaire*, pain survey*, wound*, ulcer*, coloni?* wound*, contamin* wound*, infect* wound*, coloni?* ulcer*, contamin* ulcer*, infect* ulcer*, validate*, validation, validating.

For a more detailed search strategy for each database please see Appendix 3. A secondary search was conducted via Google Scholar to look for any related articles not indexed in the above databases. The librarian screened the reference lists of all eligible articles and hand-searched the websites of relevant organisations/institutions and other sources.

3.5.2 Data management

All citations were initially exported into Endnote X9 (Thomson Reuters, New York, USA) for automated removal of duplicates, and the remaining unique citations were imported into the Covidence systematic review software (Veritas Health Innovation, Melbourne, Australia) and any further identified duplicates were removed.

3.5.3 Study selection

The Covidence systematic review software (Veritas Health Innovation, Melbourne, Australia) was used by two independent reviewers during the study selection process to screen titles and abstracts: Nicoletta Frescos (NF) and Kirsti Ahmajärvi (KA) and any conflicts were discussed and resolved at this stage of the study selection process. NF conducted the full-text review and extracted the data

using a data extraction tool developed by NF and previously tested on two articles to assess their adequacy.

3.5.4 Search results

The original search yielded 89 results, following the screen of titles and abstracts 56 were excluded, the main reason for exclusion being the wrong study outcomes, wrong populations (burns, other skin conditions) or was not related specifically to pain in chronic wounds. This generated 27 articles for full text review, eight of which were excluded as they were the wrong study design or wrong populations, and one was not in English. After searching other sources of literature one additional paper was added, thus a total of 20 articles were used for thematic review. The screening and assessment process is outlined in Figure 7.

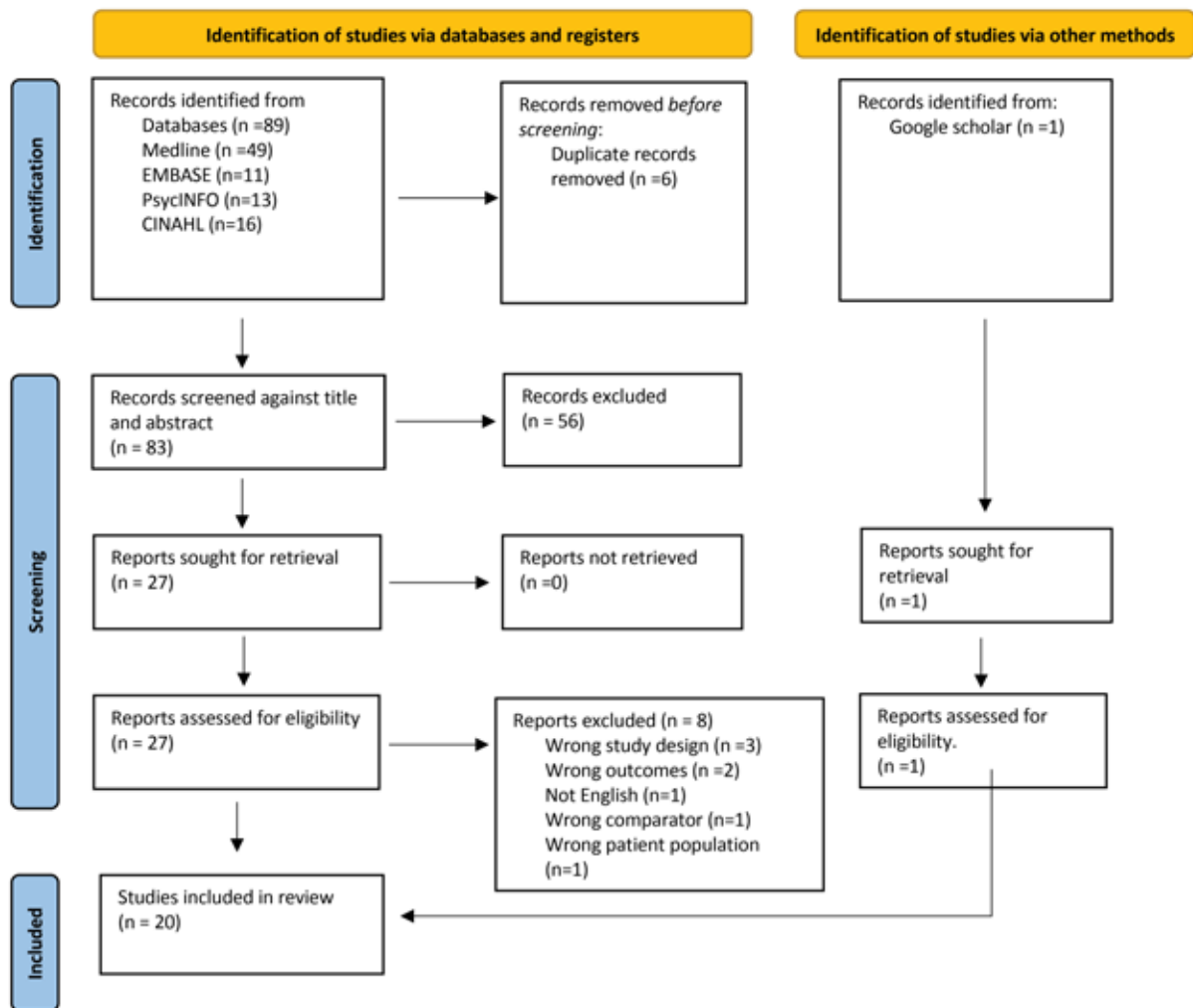


Figure 7: Flow diagram for the narrative review (modified PRISMA 2020 flow diagram)

3.5.5 Characteristics of the studies

The majority of studies were undertaken in the United Kingdom (UK), specifically England (n=6, 31.5%), followed by the Canada (n=4, 21.1%). Nine studies (47.3%) were published in the last six years (2016–2022). Regarding the types of studies, 7 (35%) were cross-sectional studies, 4 (20%) non-systematic literature reviews, 2 (10%) prospective cohort studies and 7 (35%) other methodologies including, surveys, a systematic review with Rasch analysis (Appendix 4). Six studies (30%) included QoL as a component of wound-related pain assessment.

The characteristics of the studies will be described thematically-based on the study design and outcomes and will describe the assessment tools used. The review identified six categories of studies on wound-related pain assessment tools:

- Literature review of pain assessment tools for wound related pain
- Assessment of the utility of pain assessment instruments for chronic wound-related pain
- Instruments assessing QoL and psychosocial impact of wound related pain
- Models of pain assessment and frameworks
- Generic studies on assessment of wound-related pain
- Special population specific instruments.

3.6 Pain assessment tools for wound-related pain

There were five reviews undertaken that examined the literature on wound pain assessment.^{65,66,51,67,68} Three of these reviews^{65,66,51} focused on pain in chronic lower limb wounds, one focused on wound related background pain⁶⁸ and the other⁶⁷ reviewed pain in chronic wounds as a more general topic.

Nemeth et al⁶⁵ compared the psychometric, clinical sensibility, and pain-specific properties of pain assessment tools for individuals with leg ulcer. The authors identified 54 pain assessment tools of which five met their criteria. The five tools appraised were Pain Ruler, NRS, VAS, VRS and the SF-MPQ. The Pain Ruler is a ruler that has eleven points from 0 (no pain) to 10 (excruciating pain). The patient matches the word which they feel describes their pain to the number that corresponds to their pain intensity.⁶⁹ Nemeth and colleagues concluded that each tool met the

psychometric, clinical sensibility, and pain-specific criteria to varying degrees. The most extensively used tool in the leg ulcer population was the VAS, which was used in eight studies, followed by the SF-MPQ, which was used in three studies, and the VRS used in two studies. Whilst these tools demonstrated reliability and validity, no evidence indicated that the five tools had been specifically evaluated psychometrically with the population of individuals with leg ulcers.

In an integrative review Newbern⁶⁶ examined the experience and perceptions of pain to identify the effects on QoL in patients with chronic wounds related to lower extremity vascular disease. Newbern said one of the key drivers for this study was that the lack of validated clinical assessment tools to assess pain was a barrier to adequate assessment,⁶⁶ the author also cited the findings of a study by Dickinson et al (2016) on wound pain associated with DFUs, found a difference in clinician and researcher-reported pain prevalence and that clinicians often underassess pain prevalence when they are not using a formal pain assessment tool. As part of the review, Newbern appraised the evidence related to pain assessment practices. Of the 14 studies, 11 pain instruments were reviewed. Pain specific tools (n=3) included: the Brief Pain Inventory (BPI), NRS and the SF-MPQ; tools that measured QoL (n=3): Modified EQ-5D Questionnaire, Medical Outcome Study (MOS) Pain Measures and SF-36 Health Status Questionnaire. Four tools which assessed neuropathic pain specifically: the Neuropathic Pain Scale, Neuropathic Pain Symptom Inventory and the Diabetic Peripheral Neuropathic Pain Impact Measure. Two other assessment tools in the review were included because of their relevance to the psychosocial impact of pain; the Hospital Depression and Anxiety Scale related to pain perceptions and delayed wound healing to increased depression and anxiety and the Brockopp-Warden Pain Knowledge/Bias Questionnaire which compares the provider perception of pain with the patient perception of pain. Newbern's review was narrative rather than analytical concluding that there is a lack of validated pain and QoL assessment tools for individuals with DFUs or chronic lower extremity wounds.

The aim of the scoping review by Frescos⁵¹ was to ascertain if a validated and holistic pain assessment instrument is available for use in the primary care setting to assess wound pain in chronic lower limb wounds. From the four studies that met the inclusion criteria seven of the most

commonly used generic assessment tools were identified and appraised. Only four assessment tools, the NRS, VAS, VRS and SF-MPQ were justified to be suitable for leg wounds. The review concluded that there is insufficient evidence to recommend one pain assessment tool that is suitable for all chronic lower limb wounds.

The review by Jenkins⁶⁷ focuses on the biopsychosocial perspective and highlights six pain domains. As there were no validated pain assessment tools found specifically for chronic wounds the recommended pain assessment tools discussed for each domain were based on the Outcome Measures' guidance developed by the British Pain Society (BPS), and the Faculty of Pain Medicine (FoPM) (2019). Jenkins⁶⁷ noted that tools to assess wound-related pain need to address pain quantity, physical functioning, emotional functioning and a person's global rating. Jenkins⁶⁷ recommended the use of unidimensional pain tools (which include the VAS, VRS and NRS) for pain quantity or measurement.. These are used to determine the level of chronic pain and to evaluate the effectiveness of pain management specifically.

The BPI is recommended for assessment of the impact of chronic pain on physical functioning as it is a multidimensional tool and has been psychometrically and linguistically validated in many languages⁷⁰. To assess the impact on emotional functioning the Becks Depression Inventory (BDI) and the Hospital Anxiety and Depression Scale (HADS) were deemed appropriate. These screening tools identify whether there is a need to refer the patient for a mental health review and management. Jenkins also discussed the Patient Global Impression of Change questionnaire to provide a long-term evaluation of the patient's rating on the progress of their wound pain management strategy.⁶⁷ As in the other literature reviews, Jenkins concluded that there was a lack of validated pain assessment tools for wound-related pain for individuals with chronic wounds.

The systematic review and meta-analysis by Leren et al.⁶⁸ predominately focused on wound-related background pain in individuals with chronic VLU (CVLU). Background pain is defined by Leren and colleagues as, "pain that is related to the underlying cause of the wound, local wound factors and other related pathologies, such as skin irritation", Leren and colleagues clarified that for the purposes of their review background pain was, "wound-related pain that is not

caused by dressing changes or other procedures".

In total 36 studies were included of which the majority (n=27) reported pain intensity. The common assessment tools used were NRS (n=12 studies), VAS (n=10 studies) and VRS (n=6 studies). Leren et al stated that there was variation in how the tools were applied: For example, different versions of the VRS and NRS. Furthermore, various anchor points were used, for example, zero was not always used as the lowest point, but all tools included a point that related to no pain, and for the highest point, various descriptions were used such as "*unbearable pain, worst pain ever experienced, severe pain, intense pain, most pain*". This required the authors to use standard methods for converting different rating scales for the purposes of the meta-analysis.

Other tools used for pain characteristics were the SF-MPQ (n=3 studies), the neuropathic pain questionnaire DN4 (n=1 study), and the BPI for pain interference in sleep (n=1 study). Leren et al⁶⁸ concluded that researchers and clinicians did not use standardised methods for assessing background pain in individuals with wounds. They argued that this was due to the lack of standardised methods for defining aetiology of wounds, as well as conceptualising, defining, and assessing core outcome measures such as pain.

3.7 Assessment of the utility of pain assessment tools for wound-related pain

Four studies assessed the utility of pain assessment tools for chronic wound-related pain.^{71,34,72,73}

3.7.1 Leg ulcers

Noonan and Burge⁷¹ investigated the differences in pain characteristics of venous, arterial and mixed arterial/venous ulcerations, the authors used the unidimensional scales VRS and the VAS to measure pain intensity and the SF-MPQ sensory and affective dimensions to measure the quality of pain. The COOP Chart System⁷⁴ was used to measure pain and general function, health and QoL. The COOP Function Charts are a brief screening tool to measure patient function status in the primary care setting. There are nine charts which measure:

- physical condition
- emotional condition
- daily work

- social activities
- pain
- change in condition
- overall condition
- social support
- QoL

For each chart there are five responses to choose from, each response is illustrated with a drawing that graphically illustrates the five points. High scores represent unfavourable scores on the measure.⁷⁵

Leren et al stated that the unidimensional rating scales fail to reflect the complexity of pain, thus the SF-MPQ was also used, as it provides a better description of the complexity of pain: It includes word pain descriptors and, therefore, demonstrates the multidimensional nature of pain. Furthermore, they noted that reliable and validated pain measurement scales should not be used in isolation, meaning that the assessment of other influencing factors such as physical, psychosocial and emotional factors, should be included as these impact an individual's perception of pain, which can in turn influence the effectiveness of interventions for the management of wound-related pain. This is a particularly interesting viewpoint as based on the evaluation of the systematic reviews that have been undertaken since this early study researchers seem to be focused on identifying the most valid and reliable pain assessment tool to use, which potentially perpetuates the notion that there is such a tool.

3.7.2 Pressure ulcers (PUs)

In their study of individuals with a spinal cord injury (SCI) and a PU, Roth et al³⁴ investigated the associations between pain measures, (NPRS, and MPQ dimensions) and psychosocial measures and pain (pain catastrophising and mood variables). The NPRS is a reliable and valid unidimensional assessment of pain intensity that is sensitive to changes in pain experiences⁷⁶. The MPQ is a multifactorial measurement of present pain intensity and quality.⁵¹ The SF-MPQ was found to be more sensitive to pain experience than a unidimensional rating of pain intensity as measured using the NPRS. The MPQ showed a positive relationship between increasing pain experience and advanced wound stage, whereas the NPRS did not discriminate changes in the severity of pain across the stages of wound severity.

To assess the relationship between measures of pain, depression and affective distress, Roth et al used the Centre for Epidemiologic Studies Depression Scale,^{77,78} which consists of a 20 item scale for depressive symptoms and from the Brief Symptom Inventory, the Global Severity Index was used to measure global affective distress.⁷⁹ The scale for pain catastrophising was derived from the Coping Strategies Questionnaire⁸⁰ which uses a 7 point scale to assess the individuals use of various coping strategies when dealing with pain.

Roth et al³⁴ found that the NPRS had a significant correlation with pain catastrophising ($r=0.63, p<0.05$), but did not relate to any of the other pain rating scales of the MPQ or measures of depression and distress which are commonly associated in individuals with chronic pain. The MPQ total and sensory scale were statistically significantly related to the Global Severity Index ($r=0.62$ and $p<0.05$, $r=0.61$ and $p<0.05$, respectively) and to the depression scale ($r=0.91, p<0.001$), however no association was found with the NPRS for either affective distress or depressive symptoms. Pain catastrophising was positively related to pain intensity ($r=0.63, p<0.05$) and more severe levels of affective distress ($r=0.84, p<0.001$) and more severe depressive symptoms ($r=0.89, p<0.001$). Roth and colleagues concluded that the results support the relative utility of the multidimensional MPQ for the assessment of chronic wound pain in individuals with SCI and PU when compared to the unidimensional NRS.

3.7.3 Chronic pain: nociceptive and neuropathic mechanisms

Nociceptive and neuropathic mechanisms often coexist in individuals with chronic pain.⁸¹ Two studies^{72,73} investigated assessment instruments that would be suitable in differentiating neuropathic pain symptoms to diagnose the underlying pathophysiological mechanisms of pain in different populations.

The Leeds Assessment of Neuropathic Symptoms and Signs Scale (LANSS)⁸² is a validated and reliable tool used to discriminate between neuropathic and nociceptive pain.⁸³ The LANSS includes five patient-reported symptom items and two clinical sensory testing items associated with neuropathic pain. Rutherford⁷² used the LANSS to investigate whether it is a suitable tool as an outcome measure in people with PU related pain. The psychometric and Rasch analysis was undertaken with a sample of 709

patients with PU. The findings did not support the LANSS as a reliable and valid tool for the measurement of PU-related neuropathic pain. It was unable to detect clinical change in neuropathic pain in response to treatment and may underestimate differences in pain experienced for people with severe PU. There was low correlation between the LANSS and VAS indicating that neuropathic pain as measured by LANSS was not related to pain intensity. Rutherford et al proposed that the LANSS remains primarily a screening tool as it is not suitable for outcome measures.

The MPQ uses different descriptors that can differentiate neuropathic from nociceptive pain (Appendix 1). Kogure et al⁷³ utilised the MPQ to categorise ischaemic pain into nociceptive /inflammatory pain or neuropathic pain. Kogure and colleagues examined the discriminant validity of the category by providing a list of distinct pain quality descriptors in the MPQ to dichotomise the types of pain. Kogure et al argued that the underlying pathophysiological mechanisms of ischaemic ulcer pain include a strong neuropathic component based on the underlying being related to peripheral vascular disease (including diabetic angiopathy) which is an inflammatory and nociceptive pain condition. Two categories of neuropathic pain characteristics were proposed: superficial pain descriptions of neuropathic quality and deep-somatic descriptions of nociceptive quality.

Using 78-word descriptors from the MPQ, Kogure et al investigated pain characteristics in 365 patients with neuropathic pain and 124 patients with nociceptive pain which included inflammatory pain. The diagnosis was based on the history and clinical examination including some imaging. The patients who were categorised as having neuropathic often described their pain as 'cutting' and 'burning' pain, and the coefficients of these descriptors had a high numerical value in the discriminant function. Patients categorised as having nociceptive pain frequently used word descriptors of 'squeezing' and 'dull' pain, these words are not included in the other neuropathic screening tools. Kogure et al concluded that although the MPQ descriptors were not able to distinguish between different types of pain, the MPQ has the potential to differentially diagnose various pain disorders and assist in diagnosing the underlying pathophysiology. Kogure et al also argued that this can potentially be useful in guiding the selection of appropriate analgesics for the treatment of pain.⁷³

The assessment of pain is quite complex due to the multidimensional properties and qualities of pain, measuring specific dimensions of pain can help to establish the cause of, in this instance neuropathic pain, and guide appropriate management strategies as demonstrated by Kogure's study.⁷³

3.8 Instruments assessing quality of life (QoL) and the psychosocial impact of wound-related pain

From Chapter 1 of this document, you will be aware that pain has many properties and qualities; it is multidimensional, as it is a combination of factors including sensation, emotion, nerve and memory. The assessment of pain should include the physical, psychological and emotional impact for assessing the biopsychosocial aspects of pain. Multidimensional pain assessment tools are usually used to assess chronic pain and measure how pain affects QoL. A number of studies have examined the links between pain and psychosocial factors using generic QoL assessment tools.^{40,66,84}

The assessment of different dimensions of pain and its impact on QoL in people with chronic wounds was reviewed by Jenkins.⁶⁷ The review examined instruments to assess physical functioning and emotional functioning.

In total eight multidimensional tools were discussed. The BPI was recommended to assess physical functioning. The BPI measures pain, physical and emotional functioning. It is designed to measure both pain intensity and the interference pain has on functional activities.^{85,86} The SF-BPI contains one item and uses the NRS to measure how much pain has interfered with certain aspects of life: mood, sleep, walking ability, social activity, relations with other and enjoyment of life. Several studies have shown good test-retest reliability and sensitivity to differences in pain characteristics associated with different diseases, as well its suitability for repeated evaluation of pain.^{87,88} The measure has also been shown to be valid and reliable across widely different cultural and linguistic backgrounds.⁸⁹

Jenkins⁶⁷ considered seven tools designed to measure emotional functioning, discussing two related to depression in more depth. The Beck Depression Inventory (BDI) measures characteristic attitudes and symptoms of depression and includes 21 items that ask questions about mood, self-dislike, social withdrawal and sleep disturbance.

Each item has scoring from 0–3 to reflect their intensity. Higher total scores indicate more severe depressive symptoms. Similarly, the HADS also asks a series of questions to identify symptoms of anxiety and depression. The scoring is based on two subscales anxiety (HADS-A) and depression (HADS-D). It has 14 items that is rated on a scale from 0–3. A higher total score indicates higher distress. The EuroQol 5D⁹⁰ was listed as a recommendation as the tool of choice for the measurement of QoL.

3.8.1 Venous leg ulcers (VLUs)

In a RCT on the cost effectiveness of community leg ulcer clinics, Walters et al⁹¹ compared four generic instruments for measuring health-related quality of life (HRQoL) in people with VLUs. The MOS 36-Item Short-Form Health Survey (SF-36); EuroQol (EQ); SF-MPQ and the Frenchay Activities Index (FAI) were completed by 233 patients on three occasions, initial assessment, 3 months and 12 months.

The SF-MPQ was used as a quantitative measure of pain. Walters et al evaluated the capacity of the instruments to differentiate between patients with healed or not healed venous ulcers at a point in time (discriminative properties) and measured any change in HRQoL in the patients over time (evaluative properties) in response to treatment. The SF-36 M was the most widely used generic HRQoL questionnaire at the time. It contains 36 questions measuring health across eight dimensions of physical functioning, role limitation because of physical health, social functioning, vitality or energy, pain, mental health, role limitation because of emotional problems and general health. The questionnaire generates a score from 0–100, where 100 indicates 'good health'. The EQ consists of five questions on mobility, self-care, usual activities, pain and anxiety. The FAI is intended to measure the level of independence. It is a 15-item questionnaire with three domains: ability to undertake domestic chores; leisure or work; and outdoor activities. Items are recorded for frequency of the activity in the past 3 months and for the past 6 months. The scores range from 15–60. Walters et al.⁹¹ highlighted that consideration should be given to the time interval for use of the various questionnaires. For example, all the dimensions of the SF-MPQ refer to pain in the past week except for one item *VAS Now* which asks about the status.⁹¹ Similarly, the EQ also questions the current health status on the day of the completion of the

questionnaire, whereas the SF-36 items are a combination of health status *now* and in the past four weeks. The FAI asks about the frequency of activities over 3 to 6 months. These time intervals make it difficult to interpret the relative evaluative properties of the instruments particularly when measuring short term changes and using instruments with long time interval reference periods.

Walters et al⁹¹ noted that as there is no specific assessment tool for evaluating the outcome of interventions in individuals with VLUs, the SF-MPQ can be used for short term follow up, and the SF-36 for longer term follow up, with or without the SF-MPQ.

3.9 Pain in older persons with chronic wounds

Woo⁹² explored the relationship of attachment style and pain in older persons with chronic wounds. Woo noted that according to the attachment theory:

Pain is perceived as a threat that often triggers negative emotions such as fear and anxiety. To control and regulate the impact of negative emotions, the attachment system is called into play, precipitating a sequence of events and attachment behaviours.^{92 (p171)}

The SF-MPQ was used for the assessment of characteristics of chronic wound pain, the NRS was used to measure pain intensity and the Pain Assessment in Advanced Dementia (PAINAD)⁵⁸ scale was also used. The PAINAD is an observation pain tool that assesses behavioural domains of breathing, negative vocalisations, facial expression, body language and consolability.⁵⁸ The two assessment instruments that were employed to determine the psychological and behavioural determinants were the Relationship Scales Questionnaire (RSQ), and the Shortened Anxiety Scale (SAS). The RSQ helps to discriminate three attachment patterns described as: secure, avoidant (dismissing), and ambivalent. It is a relatively easy instrument to complete in particular for older adults as it has minimal risk of response fatigue.⁹³ The SAS is a subjective measure of anxiety. It is a short form item scale that was derived from the Spielberger State-Trait Anxiety Inventory⁹⁴ which has 20 items to measure the frequency of present state anxiety and trait anxiety, being how much anxiety represents personality characteristics. The SAS includes six self-reported items; *frightened, worried, nervous, comfortable, pleasant, and at ease*.

Subjects rate each adjective on a four-point Likert scale ranging from 'not at all' to 'very much'.

Woo⁹² evaluated pain, anticipatory pain, anxiety and attachment patterns for wound dressing changes. The author compared the scores at baseline, dressing removal, cleansing, dressing reapplication and shortly after dressing changes. The results showed that participants who experienced higher levels of attachment anxiety represented by fearful avoidant and preoccupied attachment patterns expressed higher levels of anticipatory pain, anxiety prior to dressing change, and pain during dressing change than individuals who are secure with their relationship between attachment and pain. Additionally, participants with Avoidant attachment expressed the highest levels of anticipatory pain and anxiety. In contrast, Dismissive attachment style was characterised by the lowest anticipatory pain and anxiety scores. Woo (92) concluded that clinicians must be aware of the impact of personality, anxiety and anticipation of pain can have on patients' pain experiences and that there is complex relationship between pain, anxiety and attachment (self-insecurity) behaviours.

3.10 Models and frameworks for pain assessment

3.10.1 *Heal not hurt*

Heal not hurt is a wound pain assessment and recording tool developed by Barrett⁹⁵ with industry support to improve wound pain management at dressing changes. It is a two-sided document that acts as a prompt to assess pain, one side consists of four assessment tools for pain: FRS, VRS, VAS and NRS and lists key questions to prompt the basis of the assessment plan and care. The other side is a documentation sheet to record patients' pain scores before, during and after dressing changes. The tool has not been validated and has only undergone an evaluation in its pilot stage. No evidence of citations was found in other studies, nor information on the extent of its use, however it is a simple user-friendly tool that can be used by nurses to assess and manage pain and improve documentation.

3.10.2 *Toronto Symptom Assessment System for Wounds (TSAS-W)*

Maida, et al⁹⁶ developed the Toronto Symptom Assessment System for Wounds (TSAS-W) to measure pain and symptom distress associated with common wounds. The TSAS-W is a patient-rated symptom assessment tool

using the 11-point NRS to measure the poly-symptoms burden directly related to wounds. The symptoms include: pain (during dressing and /or debridement and between dressings and / or debridement); exudate; cosmetic concerns; odour; itchiness; bleeding; mass effect (swelling or oedema around the wound, bulk or mass effect from wound and bulk or mass effect from dressings); crusting and restricted movement. This was a two-phase study with the first phase identifying the most common symptoms association with wounds and the second phase was the development of the TSAS-W. The tool was developed to address a gap in palliative wound care that includes the assessment of wound-related pain and symptom issues from the patient's perspective. Although the TWAS-W shows promise, it has not been tested for reliability or validity, nor is there evidence of its use in the literature. The study emphasised the need for assessment tools that measure wound-related pain and symptom issues as highlighted by the lack of appropriate assessment tools in their literature review. The availability of these types of tools, instruments, or questionnaires may serve to promote improvements in clinical assessment and result in improved outcomes, especially when they are completed by the patient.

3.10.3 *Wound Associated Pain model (WAP)*

A prospective study of 111 participants with leg and foot ulcers was conducted by Woo and Sibbald⁹⁷ to evaluate pain control and healing trajectory of chronic wounds by applying the Wound Associated Pain (WAP) Model (Figure 8). The model was developed to assist practitioners in managing the complexity of chronic wound associated pain and integrating the principles of wound pain assessment and management into principles of wound bed preparation. The WAP model consists of three components: patient centred care; wound aetiology; and local wound factors. The NRS was the pain instrument used for the study, as Woo and Sibbald stated it is a reliable and validated tool based on the study by Herr and Mobily (1993) who found the NRS to be significantly related to the Pain Thermometer ($r=0.91$), the vertical VAS ($r=0.92$) and the VRS ($r=0.91$) in older patients, and more reliable than the VAS in people with lower education levels (Taylor and Herr 2003).

The results showed that more than 60% of participants reported wound-related pain at the beginning of the study. By applying the WAP model, significant changes were

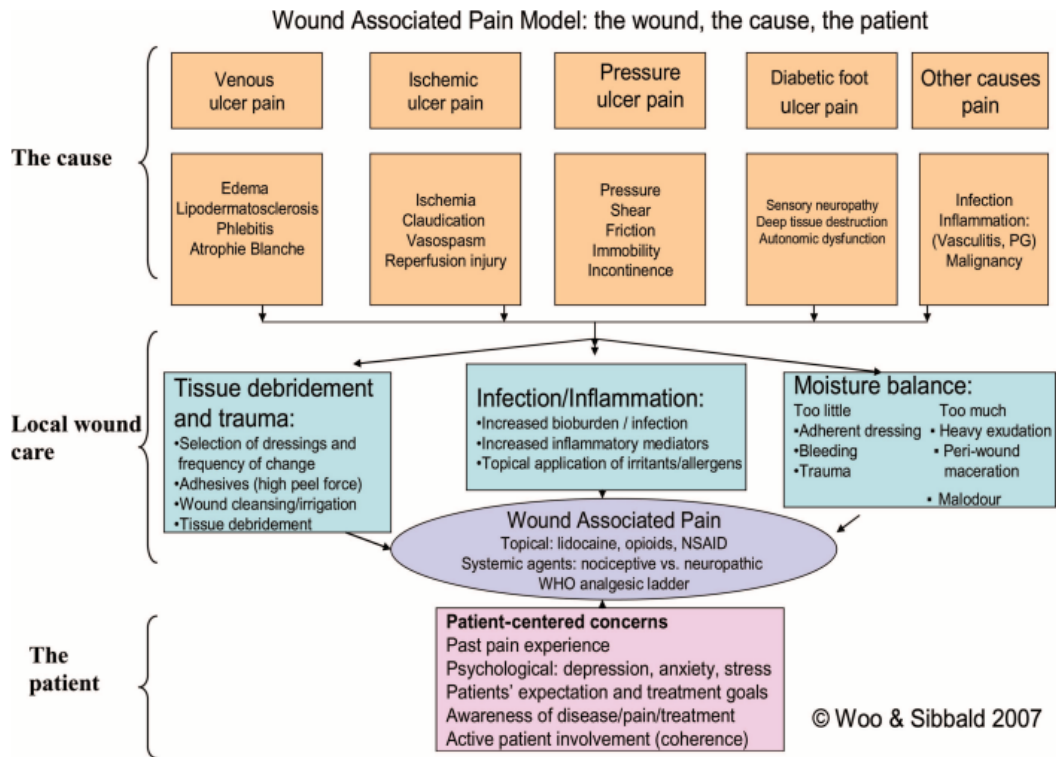


Figure 8: Wound Associated Pain Model: the wound, the cause, the patient, Woo and Sibbald (2007)⁹⁷, permission to use granted

found in pain intensity ($p < .001$), when correcting the wound cause, addressing the patient-centred concerns and using pain reduction strategies, such as careful selection and application of wound dressings, and use of topical or systemic analgesics. Woo and Sibbald⁹⁷ concluded that a comprehensive patient assessment as outlined in the WAP Model can improve wound-related pain and healing rates for chronic leg and foot ulcers.

3.11 Generic evidence on wound-related pain

In a narrative discussion regarding considerations and procedures for managing pain in patients with chronic wounds White⁹⁸ discussed key elements of pain assessment. White argued that a holistic patient assessment is paramount in understanding the patients pain experience and that no single pain measuring scale suits all patients. Once the appropriate tool is chosen, based on the needs of the patient, the same tool should be used for subsequent assessments. The assessment should include: identifying the pain type whether it is nociceptive, neuropathic or mixed; the duration and severity of pain;

the impact pain has on the patient; and pain relief rating in terms of assessment of post-pain treatment scores.

Frescos⁹⁹ undertook a survey of 1189 wound healthcare practitioners to determine how practitioners assess wound-related pain, including the types of assessment tools used and frequency of assessment. Frescos found that 63% ($n=738$) of practitioners indicated that they used a validated pain assessment tool. The most common assessment tools used were the VAS ($n=52$) and NRS ($n=328$), other tools used were the VRS, FRS and the Abbey Scale which is used for patients with dementia. When comparing the use of validated tools between the professions, nurses were more likely to use the VAS, faces scale and NRS than other professions involved in wound management. However, the majority of practitioners used a combination of different assessment tools and or methods based on the patient's cognition, language or vocabulary.

In an exploratory study Leren et al¹⁰⁰ used a combination of three tools and a question about avoidance of physical activities because of their ulcer pain was used to assess pain fluctuation in individuals with CVLU. The characteristics

of ulcer-related background pain was assessed using SF-MPQ and BPI providing scores for ulcer pain intensity, pain interference and pain qualities. Leren et al used one question from the Pain Quality Assessment Scale (PQAS) which is a validated tool for assessing various types of neuropathic and nociceptive pain. To assess how pain fluctuated during the day, the participants were asked whether their pain was intermittent, variable, or constant. This study highlights the necessity to combine several pain assessment questionnaires to measure the variety of pain characteristics for a holistic pain assessment and effective pain management.

3.12 Pain assessment tools for individuals with a cognitive impairment

According to Breuer,¹⁰¹ failure to report pain is common among those with communication difficulties. The author also noted that cognitive impairment in older people adds further complexity in determining and measuring pain. Assessing pain in patients with cognitive impairment or non-verbal patients is considered as a major challenge. Three different pain assessment tools that were specially designed to assess the pain in people with difficulty in verbally expressing pain were identified within five studies included: the FRS (n=3), the PAINAD scale (n=3) and the Abbey scale (n=1).

3.12.1 Faces Rating Scale (FRS)

The FRS, also known as the Wong-Baker FACES™ Pain Rating Scale, is a self-reporting pain scale used mainly for children and adults who cannot understand other scales. The FRS is a visual scale which uses cartoon faces ranging from a smiling face for 'no pain' to a tearful face for 'worst pain' (Appendix 1). Studies have shown that these scales are beneficial for patients who have learning difficulties or poor language skills.¹⁰² The Faces Pain Scale-Revised (FPS-R)¹⁰³ features faces with increasingly pained expressions but no smiles or tears. The scale uses a 0–10 metric with 0 = no pain and 10 = very much pain.

A cross-sectional study by Dallam et al¹⁰⁴ used both the VAS and FRS to determine the perceived pain intensity of PUs in hospitalised patients. The VAS pain scores were found to be inversely correlated with age and positively correlated with maximum pain intensity of FRS. The evaluation showed that although both tools could be used by cognitively impaired patients, they found it was easier to respond to the FRS than to the VAS, as did patients

from culturally diverse populations where English was not their first language. Freeman et al¹⁰⁵ also used the VAS and FRS to quantify PU pain in hospitalised elderly patients. They found high reliability between VAS and FRS for pain assessment in populations with diminished verbal and cognitive impairment and concluded that the FRS was a valid measure of assessing pain in the older person.

3.12.2 PAINAD

Woo⁹² and Ren et al¹⁰⁶ endorsed the use of the PAINAD scale for individuals with dementia. This is supported in the review by Jenkins⁶⁷ who also recommended the PAINAD scale as a valid and reliable tool for the assessment of pain in non-verbal older adults or individuals with cognitive impairment.

The PAINAD is used to determine the behavioural indicators of pain in cognitively impaired and non-communicative individuals.⁹² It is a five-item observational tool that assesses breathing, negative vocalisation, facial expression, body language, and the ability to be consoled. Each behaviour can be graded from 0 to 2 according to the severity of behaviour exhibited, thus giving a total score of 10, with mild pain having a score ranging from 1–3, moderate pain 4–6 and severe pain 7–10. Warden et al⁵⁸ identified that the PAINAD score has a strong correlation with an observer-rated pain severity VAS.

Woo⁹² utilised the PAINAD to evaluate the behavioural indicators of pain at before, during and after dressing and found that there is increased number of pain-related behaviours during dressing changes and that facial expressions were the most observed behaviours, followed by body movement and vocalisation. Ren¹⁰⁶ examined compliance with evidence-based criteria for individuals with DFUs, specifically in relation to assessment and management of dressing related pain. The VAS was used to assess pain and for those with cognitive impairment the Chinese-PAINAD scale was used. One of the key barriers found by Ren was the lack of standardised pain assessment tools to drive the implementation of best practice for wound pain assessment.

3.12.3 Abbey Scale

In the survey by Frescos⁹⁹ on pain assessment tools for wound-related pain, the results indicated that the FRS and Abbey Scale were common tools used by healthcare practitioners in wound care to assess pain in people with

dementia or who were unable to verbalise their pain. The Abbey Scale is specifically for use with patients with end or late-stage dementia who are unable to verbalise or articulate their needs. It is a one-page assessment tool which uses non-verbal observable cues which are then scored to ascertain the level of pain the person is experiencing.¹⁰⁷ The tool is easy to use and takes one minute to administer and document the results. The tool can also be used as a measure of effectiveness for interventions. The pain scale has been found to have high inter-rater reliability.¹⁰⁸ Although there is limited evidence in the literature to validate the clinical use of the scale, it is a commonly used in Residential Aged Care facilities for the assessment of people with cognitive impairment who cannot describe their experiences of pain coherently.¹⁰⁹

3.12.4 Face, Legs, Activity, Cry and Consolability (FLACC) Scale

Although the search strategy for this review did not find any studies on assessment of wound-related pain in children it is worthy to note the Face Legs, Activity, Cry and Consolability (FLACC) Scale (Appendix 1). This is a commonly used behavioural observation pain scale in infants and children for the measurement of three types of pain, including procedural pain, postoperative pain and acute pain has been culturally adapted into different versions for use in different clinical settings.¹¹⁰ However, the FLACC scale is limited in the capacity to discriminate between pain and distress. A systematic review evaluating the reliability, validity and feasibility of the scale found that there was sufficient evidence to support its use in post operative pain assessment¹¹¹ and in procedural pain measurement¹¹⁰ despite concerns to distinguish between pain and non-pain related distress. A study evaluating the psychometric properties¹¹² also supported the use of the FLACC scale for measuring observational pain in infants and children but stated that further studies are still needed to provide robust evidence.

3.13 Pain assessment and clinical product evaluations

Pain assessment tools are frequently used for clinical evaluations of new wound care products. Tickle⁹⁴ noted that in three different clinical evaluations of foam dressings the studies used different tools including the VAS, NRS (*sic*) and FRS. When we reviewed the study by Tickle we did not agree that it was an NRS scale, so we have

reported it in this way to indicate that this was how the author described the scale. In a clinical evaluation King and Barrett¹¹³ used a numeric scale (0–10).¹¹⁴ Other forms of pain assessment include descriptive categories of pain (no pain, mild, moderate, severe and very severe pain).¹¹⁵ Most recently Seckam et al¹¹⁵ used a qualitative phrase ‘my wound hurt’ (not at all, a little, moderately quite a lot and very much). Collectively it’s apparent that there is a tendency use unidimensional pain assessment tools to measure pain intensity in relation to product evaluation approaches. This is likely to be perhaps because they are simple, quick, and easy to administer and are sensitive to treatment effects. Additionally, they may also be closely related to the procedural pain experienced.

3.14 Summary of evidence

The evidence highlights that the assessment of wound-related pain is complex and multidimensional. Healthcare providers must determine what the most suitable assessment tool is for their patients and in doing so consider an individual’s ability to respond to the assessment. Clinicians must determine what characteristics or dimensions of pain they are seeking to assess and what is the purpose of the assessment for the specific outcome measures they are seeking. Therefore, there is no one pain assessment tool that is appropriate for all individuals, and that ‘one size does not fit all’.

Based on the evidence reviewed we would recommend the use of a multidimensional tool in conjunction with a pain intensity tool. We acknowledge that we have not conducted a systematic review, therefore it was not possible to present a GRADE evidence to decision (EtD) framework¹¹⁶ which is a systematic and transparent approach to making well informed healthcare choices. Nevertheless, the recommendations for clinical practice and healthcare professionals are summarised on the best available evidence for clinical practice as well as from clinical experience and expertise. Table 7 summarises the most commonly used tools in clinical practice and a summary of recommendations for pain assessment for individuals with wound-related pain is shown in Table 8.

Table 7: Most commonly used tools in clinical practice

| Pain assessment tool | Description | Pain domain | Type of tool | Indicators |
|-------------------------------------|---|--|------------------|--------------|
| Generic pain assessment tools | | | | |
| Visual Analog Scale (VAS) | A horizontal 100mm line anchored by words at each end, indicating the extremes of pain, from no pain to worst possible pain. A mark is placed on the line at the point that represents the level of pain experienced | Intensity | Unidimensional | Generic tool |
| Numerical Pain Rating Scale (NPRS) | Eleven point numeric scale ranges from zero for no pain to ten to represent pain at the other extreme e.g. worst pain imaginable. Can be administered verbally or graphically. Respondent is asked to indicate the numeric value on the segmented scale that best describes their pain | Intensity | Unidimensional | Generic tool |
| Pain Ruler | A ruler that has 11 points from zero (no pain) to ten (excruciating pain). The patient matches the word which they feel describes their pain to the number that corresponds to their pain intensity | Intensity | Unidimensional | Generic tool |
| Verbal Descriptor Scale (VDS) | Five point verbal description of pain "none, mild, moderate, severe and overwhelming". The patient is asked to choose the word that best describes their pain. | Quality | Unidimensional | Generic tool |
| Multifactorial pain assessment tool | | | | |
| Brief Pain Inventory (BPI) | Incorporates the NRS to measure pain intensity and seven questions to measure the interference pain has on an individual's daily functioning. Both outcome measures use an 11 point scale for the measurements, of pain intensity: 0=no pain, 10=pain as bad as you can imagine; and for interference 0=does not interfere, 10=completely interferes. The higher the score the greater the pain or interference of pain with activities | Intensity and impact on daily functional activities. | Multidimensional | Adults |

| | | | | |
|---|--|-----------------------|------------------|---|
| Short Form -McGill Pain Questionnaire (SF-MPQ) | Consists of 15 pain descriptors and evaluates the subjective experience of pain and quantifies pain into three dimensions: sensory, affective and evaluative qualities of pain. The participant selects the descriptors that describe their pain, and a score is allocated on a four point scale ranging from none (score=0) to severe (score=3) intensity. The VAS is utilised to measure present pain intensity. | Intensity and Quality | Multidimensional | Commonly used in older patients |
| Special populations | | | | |
| Wong - Baker FACES™ Rating Scale Or Faces Rating Scale (FRS) | Facial expression illustrations to outline scale of pain severity. Zero point 'happy face' represents the absence of pain, a 10 point 'crying face' represents the worst possible pain. Faces in between represent scores of 2, 4, 6 or 8. Patients choose the face which best describes how they feel. | Intensity | Unidimensional | People aged 3 and over or adults who cannot understand other scales. |
| Faces Pain Scale – Revised (FPS-R) | Modified Wong-Baker FACES scale. Visual scale using cartoon faces ranging from a smiling face for 'no pain' to a distressed face for 'worst pain'. It excludes the smiley faces and crying face. The words "happy" and "sad" are not to be used. | Intensity | Unidimensional | People aged 3 and over or adults who cannot understand other scales. |
| PAINAD Pain Assessment in Advanced Dementia | Consists of five behaviours which need to be observed; breathing, negative vocalisation, facial expression, body language and consolability. The total score ranges from 0–10 Score of 1–3=mild pain, 4–6=moderate pain and 7–10=severe pain. | | Multidimensional | Verbal and non-verbal patients with dementia or cognitive impairment. |

| | | | | |
|--|--|-----------------------|------------------|---|
| Abbey Pain Scale | It is a one-page assessment tool which uses non-verbal observable cues which are then scored to ascertain the level of pain the person is experiencing. It is used as a movement-based assessment. There are six categories, each levelled on a four point scale (Absent=0; Mild:=1; Moderate:=2; Severe=3), with a total score ranging from zero to 18. The total score is interpreted as the 'probability' that the person is experiencing pain (No pain=0-2; Mild=3-7; Moderate=8-13; Severe=14+). Immediately after movement the patient's pain is assessed against the scale. It does not differentiate between distress and pain. | | Multidimensional | Patients with end or late-stage dementia who are unable to verbalise or articulate their needs |
| Neuropathic | | | | |
| Neuropathic Pain Scale | Consists of ten specific qualities association with neuropathic pain. It assesses two global pain domains (pain intensity and unpleasantness). It covers six pain qualities (sharp, hot, dull cold, sensitive, and itchy pain and two pain locations (deep and surface pain). Scores are based on patient responses to questions about pain intensity, zero indicates no pain, ten indicates the most imaginable pain. Maximum total score is 100. | Quality and intensity | Multidimensional | Discriminates between neuropathic and non-neuropathic pain. Only used in patients who have already been diagnosed with neuropathic pain |
| Douleur Neuropathique en 4 Questions (DN4) | Comprised of two interview questions (sensory and pain descriptors) and two items based on clinical examination. The total score is the sum of ten, scores $\geq 4/10$ indicate neuropathic pain | Quality and cause | Multidimensional | Screening for neuropathic pain |
| Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) | Comprised of five symptom-related pain questions and two clinical sensory examinations for the presence of allodynia and altered pin prick threshold. | Severity and cause | Multidimensional | Assesses difference between neuropathic and nociceptive pain |

Table 8: Summary of recommendations for pain assessment for individuals with wound-related pain

| Type of wound related pain | Suitable methods of pain assessment | Concrete tools and scales and timing | Strengths (S) and limitations (L) of the assessment method | Competent qualified person | Notes – special circumstances, special patients group (tools for assessment) |
|----------------------------|--|---|--|---|---|
| Acute and chronic pain | <p>Unidimensional scales and tools are usually used to assess pain intensity and change as a result of interventions (procedural pain), in relation to physical activity (physical strain) and related wound manifestations, as well as the treatment and healing process</p> | <p>Visual Analogue Scale – VAS Numeric Rating Scale – NRS Verbal Rating Scale – VRS Visual Descriptor Scale – VDS Face Pain Rating Scale – FRS</p> | <p>S: quick, easy to use, mostly no problems with inter-rater reliability and intra-rater reliability L: does not allow user to differentiate or discriminate changes in the severity of pain across the stages of wound severity</p> | <p>Physician General Nurse Nurse specialist Occupational therapist Physiotherapist/ Occupational Therapist* Pharmacist Podiatrist *Sometimes referred to as an Ergotherapist in some countries</p> | <p>Elderly and cognitively impaired patients: PAINAD Abbey Scale (high inter-rater reliability with dementia and Faces Rating Scale (FRS)) Note: comorbidities and/or medications can alter response to pain Children: The Faces Pain Scale -Revised and the Wong-Baker FACES® Pain Rating scale were originally created for children, now these scales are used for people aged three and older to facilitate communication of pain. The FLACC scale or Face, Legs, Activity, Cry, Consolability scale is a measurement used to assess pain for children between the ages of 2 months and 7 years or individuals who are unable to communicate their pain. Note: does not distinguish between distress and pain. IMPORTANT: for VRS the same anchor points are not always used (e.g. all include an item for 'no pain', some also include a numerical rating of zero to indicate no pain and for the highest point, various descriptions could be used such as "unbearable pain, worst pain ever experienced, severe pain, intense pain, most pain"</p> |

| | | | | | |
|---|--|--|---|--|---|
| <p>Chronic pain (influencing QoL and basic daily activities)</p> | <p>Multidimensional pain assessment tools are usually used to assess chronic pain and measure how pain affects quality of life (mood, sleep, walking ability, social activity, relations with other and enjoyment of life).</p> | <p>BPI: recommended to assess physical functioning (NRS compared to the influence/interference with affects to QoL). SF-MPQ: provides a better description of the complexity of pain as it includes word pain descriptors and therefore demonstrates the multidimensional nature of pain. Modified EQ-5D Questionnaire measures quality of life Medical Outcome Study (MOS) Pain measures emotional functioning SF-36 Health Status Questionnaire measures emotional functioning Evaluation of the emotional status: Becks Depression Inventory (BDI) Hospital Anxiety and Depression Scale (HADS) Patient Global Impression of Change questionnaire measures patients self-report of their global rating Evaluation of the psychological status: HADS related to pain perceptions and delayed wound healing to increased depression and anxiety Shortened Anxiety Scale (SAS) Brockopp-Warden Pain Knowledge/Bias Questionnaire</p> | <p>S: valid, reliable, comprehensive assessment, allow to assess the positive relationship between increasing pain experience and advanced wound stage L: need for staff training, regular audits of appropriate assessment and use of tools, for people with special needs (children, elderly, people with cognitive impairment) it is appropriate to involve other members of the multidisciplinary team (e.g., psychologist)</p> | <p>Psychologist Specially educated General nurse Nurse specialist (tissue viability nurse)</p> | <p>The MPQ showed a positive relationship between increasing pain experience and advanced wound stage, whereas the NPRS did not discriminate changes in the severity of pain across the stages of wound severity Patients with neuropathic pain: Leeds Assessment of Neuropathic Symptoms and Signs scale (LANSS) – discrimination between neuropathic and nociceptive pain Neuropathic Pain Scale Neuropathic Pain symptom inventory Diabetic Peripheral Neuropathic Pain Impact Measure</p> |
| <p>Background pain</p> | <p>May have features of acute and chronic pain, based on the main manifestations e.g., itching, burning, other irritation of tissues, etc.) the relevant assessment tool should be used (uni- or multi-dimensional)</p> <p>Pain that is related to the underlying cause of the wound, local wound factors and other related pathologies, such as skin irritation', and pain which is not caused by dressing changes or other procedures'</p> | | | | |

4. Physical therapies for wound-related pain management

4.1 Introduction

This chapter reviews evidence related to physical therapies for wound-related pain management and chronic wounds. It is important to note that the definition of physical therapy according to the search strategy did not limit the evidence to Physical Therapy which refers to the profession. The results are based on five articles retrieved from the L OVE platform. An additional three articles identified from the references within the reviews are also discussed. These articles examined the use of topical analgesics for management of anticipatory pain, debridement and procedural-related pain and the potential effect of negative pressure wound therapy (NPWT) in reducing inflammation and by association, pain. In keeping with the theme of ‘procedural-related’ pain, evidence associated with the use of dressings is also reviewed in this chapter. The evidence for this aspect was identified by hand-searching of the literature. A summary of recommendations from the evidence, clinical experience and expertise is provided at the end of the chapter to facilitate implementation into clinical practice.

4.2 Method

4.2.1 Search method

The search strategy aimed to find systematic reviews related to the role of Physical Therapies in the holistic management of wound-related pain. We searched the L OVE platform, which collects systematic reviews retrieved from the systematic reviews database Epistemonikos⁷ and allocates them to specific L OVEs and questions⁸. We conducted a search of L OVE for *wounds* and *burns* on 17 June 2022, and retrieved relevant systematic reviews using the filters for *physical therapy* and *rehabilitation*. There were no language, publication year or publication status restrictions.

We screened the reference lists of all eligible systematic reviews and hand-searched websites of relevant organisations/institutions and other sources.

4.2.2 Inclusion criteria

Systematic reviews of pain and chronic wounds, which

discussed an intervention related to management of wound-related pain were included.

4.2.3 Exclusion criteria

Acute wounds, burns (burn injuries)

4.2.4 Selection of studies

Retrieved titles and abstracts were exported into Rayyan⁵² by an information specialist, Simona Slezáková. The title and abstracts were screened in duplicate and independently by two authors, Kirsti Ahmajärvi (KA) and Nicoletta Frescos (NF). The blind mode within Rayyan was kept on until both authors had completed the first screening. Subsequently, the blind mode was turned off to allow the authors to view each other’s decisions. The authors then met to resolve the disagreements and agree which results would move to the second stage of a full-text review of selected articles. Full-text screening was conducted similarly to the title and abstract screening. Following the full-text screening a list of studies for inclusion / exclusion was created. The original search yielded 185 results. Following the title and abstract screening 171 were excluded, the main reason for exclusion being the wrong outcome or population. This generated 14 articles for full text review. Nine full texts were excluded as they did not have the relevant outcome. Five reviews met the inclusion criteria and were included in the analysis (Appendix 5). Moreover, hand-searching retrieved three more articles (Appendix 6). Finally, 8 systematic reviews were included in our literature review. The screening and assessment process is described in detail in the flow diagram (Figure 9).

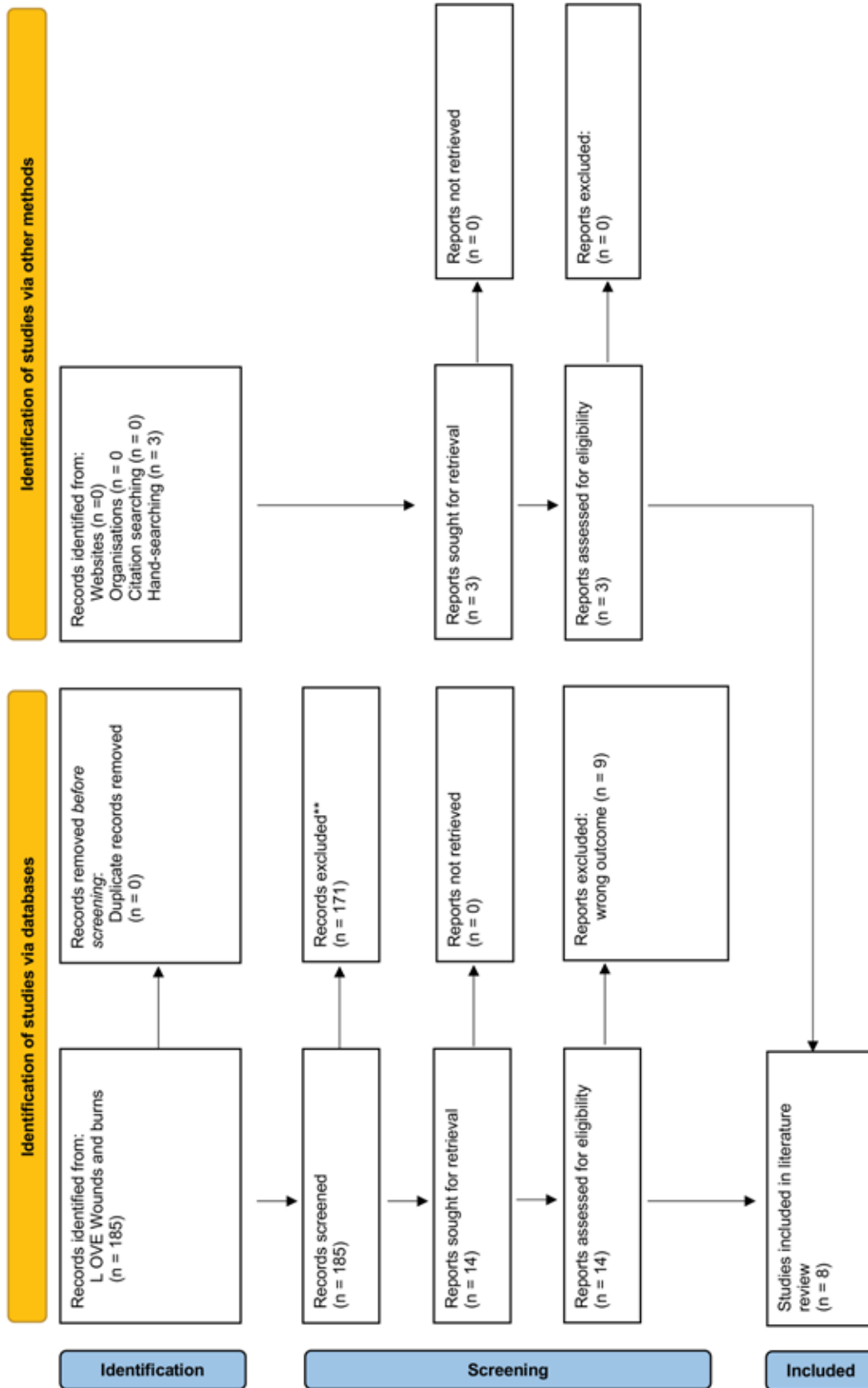
4.2.5 Data extraction

Relevant data were extracted from the included reviews by KA and NF.

4.3 Background

The World Health Organization analgesic ladder is widely used to guide the management of acute and chronic pain¹⁷ for non-specialists. This chapter does not discuss the use of drug treatments for the management of pain as this was considered to be outside the scope of this document.

Figure 9: Flow diagram of the screening and the assessment process for physical therapies, (modified PRISMA 2020 flow diagram)



Our recommendation would be to consider referring the individual to a specialist when the usual non-specialist interventions have failed, or where the pain is poorly controlled, and the individual is experiencing distress.

We would also like to point out that based on the literature search methodology undertaken for this chapter the use of honey as an intervention for management of wound-related pain was not retrieved in relation to physical modalities. Instead, the evidence to support the use of honey will be examined in the Complementary and Alternative Approaches chapter, which was according to the indexing within Epistemionikos.

4.4 Results

4.4.1 Characteristics of the systematic reviews via Rayyan

Five reviews included a total of 56 studies. The date range of the include studies was 1996–2018 and the number of included articles varied in the reviews between 2–25. A total of 2492 patients were included, and the studies were conducted in the following countries: Netherlands, Ireland, Australia, Poland, United States of America, England or unspecified English-speaking countries: however not all the studies reported the geographical location. Studies included all types of the ulcers; vascular, venous, PU, DFUs etc. Exclusion criteria was acute wounds and burns, but if the study included both chronic and acute wounds it was included with the evidence on chronic wounds being examined.

4.4.2 Characteristics of the systematic reviews via hand-searching

The three additional systematic reviews retrieved by hand searching included a total of 123 articles which were published 1990–2022 and were conducted in the following countries: England, Poland, USA, Switzerland, Canada, Spain, Scotland, Australia, New Zealand, Brazil, China, Denmark, France, Sweden. Of the total number of studies which reported sample size /number of participants there were 4689 participants, with samples ranging from 1–280.

Collectively, the evidence provided data from 179 studies published between 1990–2022 with a total sample size of over 7000 patients and included at least 15 different countries.

4.5 Physical therapies

Physical therapies for management of wound-related pain include physical therapy and physical activity, careful consideration when undertaking dressing changes: such caution in the procedure itself and also using atraumatic dressings. Impregnated, medicated dressings may also be used and, of course, the use of analgesics taken before or after a procedure is also an important factor. The evidence reviewed for this chapter also indicated that there may also be a role for the use of NPWT in the management of wound-related pain. Additionally, the use of extracorporeal shock wave therapy (ESWT) is discussed as a treatment method for chronic wounds with specific reference to its use for wound debridement, as it has been reported to be less painful.

Yim et al's¹¹⁸ systematic review examined the effect of physical therapy on wound healing and QoL in patients suffering from VLU. Ten studies met the criteria for inclusion, which focused on the role of exercise on ankle joint mobility. Interventions discussed included, walking, heel-raises in standing position, tip-toe exercise, cycling, use of elastic (sic) bands (taken to mean resistance bands in this context) and use of a treadmill. Supervision by a Physical Therapist or Physical Therapy Assistant or a nurse were also considered as physical therapy according to this review.

Tools for measuring QoL included domains related to pain, for example, the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36), and the NHP. Disease specific tools were also used and included the Chronic Lower Limb Venous Insufficiency and Venous Insufficiency Epidemiologic and Economic Study Questionnaires.

Of the 10 studies included in the review only two (Davies et al 2007 and Zajkowski et al 2006) reported reduction in pain after exercise, however a key finding was that pain was the main domain affecting QoL and in turn physical exercise had a positive effect on QoL. The overall conclusion was that improvements in HRQoL were related to improvement in pain, rather than wound healing. However, it is known that the presence of pain can cause stress and anxiety which in turn can have a negative effect on wound healing (see Chapter 2: Multidimensional Nature of Pain). Therefore, the findings of the review by Yim et al¹¹⁸ strengthens the evidence that management of wound-related pain is important to improve patient outcomes.

Smith et al¹¹⁹ also investigated the effect of exercise on wound healing in patients with VLU. Smith and colleagues evaluated exercise as adjunctive or additional therapy with compression therapy. Six articles published between 2009–2017 were included. Participants were from outpatient clinics, hospitals and patients living at home. Outcomes of interest across the studies included time to heal, size and recurrence of the wound, pain, QoL, adverse events and economic aspects were also considered.

Two studies cited in the review by Smith et al¹¹⁹ (Meager et al (2012) and Szewczyk et al (2010)) characterised pain as a specific outcome measure. Meager et al studied the use of an exercise programme in addition to compression compared with compression therapy alone. Similarly, Szewczyk et al studied the impact of an extensive supervised exercise programme (ESEP). The studies included 32–35 participants respectively and the programmes lasted for 9–12 weeks. In the study by Meagher et al the intervention group were asked to exercise at home undertaking a minimum of 10,000 steps daily while in the Szewczyk et al study the participants were asked to walk 3km daily and additionally perform 3 times 15 sets of heel raises, foot movements or alternative foot exercises. The results from both studies showed that there was no increase in pain levels after increasing the level of daily exercise.

The 10,000 Steps programme used a VAS to assess pain and the ESEP programme used a three point pain scale where 0=no pain, 1=moderate and 2=severe pain. Smith et al¹¹⁹ noted that a limitation of these, and the other studies, was the lack of validated pain assessment tools with the majority of studies using self-reported measures. Overall, there was a lack of data reported to facilitate scrutiny of the results and this limits the conclusions that can be drawn.

While these studies provide evidence that pain did not increase during or after exercise, the implications for the role of physical exercise as a strategy for management of wound-related pain is less clear. Nevertheless, wound healing was a primary outcome of the studies and physical therapy has been discussed as one approach to help support healing. Equally pain was discussed as one of the major factors that can have a negative effect on an individual's QoL. Collectively this evidence supports the idea of the multidimensional nature of pain and the need to consider the physical, social, and psychological factors that can affect the experience of pain.

4.6 Topical analgesics

Topical analgesics are commonly used when treating anticipatory pain during procedural treatments in wound care. For example, to carry out a painful dressing change or when wound debridement is required. The effectiveness of topical analgesics has also been investigated as an intervention for pain treatment.

Purcell et al⁵⁵ undertook a review to examine the effectiveness of topical analgesics and local anaesthetics in the treatment of pain of patients with chronic leg ulcers. They identified a total of 406 articles of which 23 met the inclusion criteria. Many of the studies were conducted in Europe (n=20). The range of participants varied across these studies from fewer than 25 up to 835 in one study. Purcell and colleagues categorised the results into two main groups; those who had topical analgesics (n=10) and the others who had local anaesthetics (n=13).

Assessment of pain in the studies which examined the use of topical analgesics (n=10) was undertaken using a variety of methods including, numeric rating scale (NRS), VAS, visual rating scale and numeric box scale. The type of wounds included in the studies were mostly venous in origin and the intervention consisted mostly of foam dressings with ibuprofen (dose of 0.5mg/cm²). According to six studies the use of impregnated foam dressings reduced pain compared to placebo or standard care. However, five studies reported adverse events related to ibuprofen, which were mainly related to irritation of the skin, allergic reactions, bleeding, and increased pain. The use of a topical morphine gel was also investigated in three studies. Morphine gel was applied to the wound bed daily in doses of 0.5mg/cm², 10mg and 0.5%/g though it was difficult to determine the effectiveness due to the small sample sizes.

In the studies examining the effect of local anaesthetics (specifically prilocaine and lidocaine) for management of pain related to debridement of chronic wounds the results indicated a statistically significant effect on reduction of pain. The doses used were prilocaine 2% or 5% and lidocaine 10%. However, some studies used larger doses (up to 150g lidocaine). Three of the studies investigated the toxicity levels after treatment and concluded that safe doses are 2% and 5% of lidocaine/prilocaine cream. Across the studies the average application time was 30 minutes; however, in two studies this was extended to 45 minutes

or 60 minutes. Adverse events reported included irritation, burning, itching.

The results of the review by Purcell et al⁵⁵ suggested that the use of a topical analgesics in the form of an impregnated ibuprofen dressing or lidocaine/prilocaine cream can reduce chronic leg ulcer pain, yet the evidence is inconsistent. Furthermore, there was a lack of sufficient data to support the use of opioid impregnated gel for topical pain management. With regards to the use of topical anaesthetics, the evidence for their use in reducing pain associated with debridement indicates that lidocaine/prilocaine gel has the strongest evidence.

Further evidence related to management of wound-related pain associated with debridement will be explored in more detail in a subsequent section.

In a recent scoping review examining the use of topical therapies in the management of pain in malignant fungating wounds (MFWs), Costa Ferreira et al⁶ concluded that there was a lack of evidence for the effectiveness of existing wound-related pain management strategies.

Costa Ferreira and colleagues reviewed 796 articles of which 70 studies were included for analysis. The majority of the studies were in English (88.6%) and were undertaken in the UK (n=18, 24.3%) or United States (n=16, 22.9%). Almost half of the studies (45.7%) were non-systematic reviews, one third (28.5%) were case studies and 25.8% other types of studies (controlled trials, systematic reviews, cohorts, guidelines and surveys). The sample sizes were between 1–60 patients. The population was adults over 18 years old who were from different settings, including home care, long-term care, palliative care units and hospitals.

Costa Ferreira et al identified 20 different therapies for pain management. The most commonly used interventions included wound dressings (58.6%), analgesic drugs (55.7%), topical antimicrobials (25.7%), skin barriers (15.7%), cryotherapy (5.7%) and NPWT (4.3%). Costa Ferreira et al⁶ grouped the therapies into two main categories: topical therapies which were applied in the wound; or in the periwound skin.

From the RCTs reviewed, positive outcomes for the management of wound-related pain were associated with the use of lidocaine/prilocaine 2.5%, morphine gel 0.2% as analgesics.

The results also showed that antimicrobials such as, metronidazole 0.8%, polyhexamethylene biguanide (PHMB) with betadine 0.1% solution, octenidine solution, honey and silver had a positive effect on reported pain. Costa Ferreira et al⁶ noted that a combination of topical therapies to address high levels of exudation and also to avoid adhesion of dressings to the wound bed also need to be considered as approaches to pain management.

Of the total number of articles reviewed (n=70) 26 studies reported on the use of non-adherent dressings for pain management. Of note is that all studies combined the use of dressings with other interventions for pain management, for example opioids, topical anaesthetics, and antiseptics. The use of hydrogel dressings was examined in 11/70 of the studies, with the consensus view being that these reduced pain by maintaining moisture on the wound bed. Hydrogel dressings were also combined with opioids, anaesthetics, and antiseptics in some studies. Ten studies reported the use of ‘absorbent’ dressings in combination with other products to control exudate, the view being that this strategy helped to reduce the risk of moisture-related dermatitis and consequently helped to manage pain. The use of dressings impregnated with ibuprofen as an anti-inflammatory dressing were also discussed as an option.

Like the previous review by Purcell et al,⁵⁵ Costa Ferreira et al⁶ examined the use of topical application of opioids and topical anaesthetics to the wound bed as a strategy to manage pain. Of the 70 studies reviewed, 33 examined one or both interventions. Regarding topical anaesthetics, the use of lidocaine, prilocaine, benzocaine and tricyclic anaesthesia were mentioned but no information was provided on the formulation and dosage.

Of the studies examining the use of topical antimicrobials (n=3) the most common interventions included, metronidazole, silver sulfadiazine, nanocrystalline silver, honey, and topical antiseptics. The justification from the authors of these studies being that the main effect of using these preparations was their potential for killing micro-organisms which they said reduced the risk of wound infection. Pain was included as an outcome measure in the studies. While these studies were not examining the management of wound-related pain *per se* it is recognised that pain, and/or increased pain is associated with the presence of a wound infection¹²⁰ (therefore clinicians need to determine whether the presence of a wound infection is the underlying cause of the wound-related pain to establish the most appropriate intervention(s).

With regards to periwound management the use of topical therapies (such as zinc oxide, silicone, dimethicone, petrolatum, acrylate, cyanoacrylate, hydrocolloid and vitamin-rich ointment [A and D]) was addressed in 11 studies. Overall, it was suggested these have a positive effect on pain, however there was a lack of information further regarding assessment of pain and no data were provided to support this claim. Whilst the focus of the current document was wound-related pain specifically, periwound damage can contribute to pain and discomfort¹²¹ therefore strategies to address periwound pain must also be taken into consideration in the wider context of 'wound-related pain'.

A major limitation of the studies in the review by Costa Ferreira et al¹⁵⁶ was the variation in pain assessment tools used (Visual analogical scale, Numeric verbal scale, McGill's questionnaire and assessment by categories). This makes it difficult to determine the impact of interventions for the management of wound-related pain. Yet pain is one of the most significant symptoms affecting QoL among people suffering from MFWs, therefore to determine the clinical effectiveness of different interventions for MFW with regards to wound-related pain specifically there is also a need for a more standardised approach to pain assessment: One cannot be viewed in isolation of the other.

4.7 Debridement

Wound-related pain is commonly associated with debridement procedures^{122,123} which encompass; surgical and sharp techniques as well as non-excisional methods such as, scrubbing, washing, enzymatic, hydro surgery, maggot therapy, high-pressure irrigation, and use of ultrasound. Several debridement options may be associated with what is referred to as 'procedural-related pain', where the wound may be painful just for the period the procedure is being undertaken, and painless afterwards. For the purposes of this document, it was felt to be important to address procedural-related pain in the wider context of wound-related pain.

Ramundo and Gray¹²⁴ reviewed literature to study ultrasonic mist debridement for different aetiologies of wounds including venous, ischaemic, neuropathic, trauma origin and hard-to-heal ulcers. Ramundo and Gray identified only two studies which provided a total of 203 participants. Ramundo and Gray found no statistical difference in the wound healing between the groups treated

with conventional methods and low-level ultrasonic mist therapy. Pain was treated with local anaesthetics when reported by patients, however pain was not a primary or secondary outcome of the studies.

Herberger et al¹²⁵ investigated the use of ultrasound-assisted debridement (UAD) versus surgical debridement (curettage), in an RCT (n=67). Herberger and colleagues used a VAS scale to assess pain before, during and after the treatment. Pain was considered as a main outcome measure alongside patient benefit and tolerability, and wound healing. Herberger et al used a topical local anaesthetic cream (containing lidocaine and prilocaine), applied to the wound bed 60 minutes before the procedure, and recorded whether patients also required the use of additional oral analgesia. The results showed that there was no significant increase in pain in either group, however in the intervention group, which had UAD, the baseline data shows that patients had higher pain scores pre-procedure, yet they did not experience more pain than the patients receiving regular treatment post-procedure. There were also no significant differences between the groups in efficacy or tolerability of the techniques.

Chang et al¹²⁶ investigated the use of low-frequency ultrasound (LFU) as a debridement method for chronic wounds and found that less pain was reported with this technique. Chang and colleagues discussed that ultrasound is a method which uses acoustic energy to remove dead tissue in the wound bed, thereby promoting wound healing. Furthermore, they discussed that the proposed mechanism of actions of ultrasound are both mechanical and thermal which can have a positive effect at a cellular level.¹²⁶ Low-hertz Ultrasound (20–60kHz) has been found to reduce exudate and has a positive effect on the presence of biofilm on the wound.¹²⁷ Furthermore an early study by Schoenenbach and Song,¹²⁸ cited by Ramundo and Gray¹²⁴ reported that ultrasound decreased the level of *Pseudomonas* in the wound bed of patients with burn wounds. The studies in the review by Chang and colleagues examined the use of LFU in patients with PUs, DFUs, arterial and venous ulcers, surgical and/or traumatic ulcers and burn wounds.¹²⁶

Chang et al¹²⁶ reviewed 25 studies providing a total of 850 participants. Studies were heterogenous in design and no meta-analyses were found. The majority of the studies evaluated the use of MIST® Therapy (n=19), which

is the most often used LFU therapy. In seven studies there was a reported reduction in wound pain when using LFU. Compared with other standard debridement techniques there were no differences between the modalities with regards to removal of fibrin and necrosis, and all showed positive effects on granulation of tissue formation and QoL.

It is acknowledged that the use of UAD is not indicated for the management of wound-related pain, however the current document considers pain to be a central feature of QoL measures, therefore these reviews support the importance of considering the potential consequences of procedural-related pain when selecting the most appropriate debridement method.

4.8 Negative pressure wound therapy (NPWT)

NPWT has a number of reported effects including reduction of wound exudate and inflammation, it also enhances angiogenesis and epithelialization thereby reducing wound healing time.¹²⁹ However, NPWT can be associated with pain related to the system and the dressing (foam/filler) used and whether this dressing adheres to the wound bed.¹³⁰ As discussed in the chapter examining the multidimensional nature of pain this can have a significant impact on an individual's well-being, which brings to the fore the importance of considering psychological aspects in the wider context of wound-related pain.

Upton and Andrews¹³⁰ reviewed the use of NPWT examining the outcomes of pain and trauma specifically. The authors included 30 studies (n=152 participants) and found that gauze-based filling was less painful than foam as pain was associated with adherence of the foam into the wound bed. In a previous study by Upton et al¹³¹ which included 43 patients in an out-patient setting the authors identified a significant reduction in pain when using atraumatic dressings compared to conventional dressings. In a multicentre study Teot et al¹³² investigated 66 patients receiving 1145 days NPWT treatment combined with a non-adhesive, non-occlusive dressing. Pain was assessed during each treatment procedure and at two consecutive dressing changes, however the pain assessment tool used was not reported. Upton and Andrews discussed that if there was less trauma associated with the NPWT dressing change the procedure was less painful. The same authors reported that pain related to NPWT also reduced over time, however this was not a statistically significant finding.

Furthermore, the authors discussed that because NPWT has a positive influence on the time to wound healing this in turn has a positive impact on the experience of pain.

The systematic review by Costa Ferreira et al⁵⁶ examined the use of NPWT in the management of MFW. However, there were only three studies providing a total of six patients. As NPWT is contraindicated in patients with MFW and the strength of evidence for this population is low we were unable to make any recommendations based on this systematic review.

4.9 Extracorporeal shock wave therapy (ESWT)

ESWT has been used in the treatment of urinary stones however its use has also been reported in the treatment of chronic wounds.^{133,134} ESWT is biphasic, high-energy acoustic pulses which create transient pressure waves in three-dimensional space, and it rapidly rises pressure which is applied to tissue without causing any damage.¹³⁵ The effect of the device is to produce low energy pulses which can penetrate the skin up to a 3 cm depth.

Dymarek et al¹³⁶ studied the efficacy of ESWT in wound healing. The authors discussed that ESWT has an anti-inflammatory effect, enhancing tissue granulation, improving blood flow perfusion, angiogenesis and re-epithelialization. The authors also discussed that the therapy reduces necrotic tissue and time to complete wound closure. Dymarek and colleagues identified 393 articles published between 2000–2013 of which 13 studies met the criteria giving a total sample size of 919.

Overall, the results showed that ESWT was considered a safe, mostly painless non-invasive treatment method, however pain was self-reported, and no pain assessment tools or scores are mentioned. The included studies indicated that ESWT has been used as an adjunctive treatment for different aetiologies of wounds including VLU, DFU, arterial insufficiency ulcers, PUs, acute burns wounds, surgical wounds and post-traumatic wounds. According to the review no local anaesthesia or analgesia were needed while ESWT was being carried out. However, some adverse events were reported including pain and bleeding. The primary outcome in the studies reviewed was wound healing rather than wound-related pain specifically, however as the mechanism of action of the therapy is mostly anti-inflammatory it was considered applicable to the topic.

4.10 Procedural-related pain: role of dressings

Additional sources of evidence that were reviewed included articles provided by the companies sponsoring this document.

A total of 62 references were provided by three companies, of these 55 were available as full text. The full-text articles were reviewed by Alisha Oropallo and Samantha Holloway independently. The criteria for inclusion were that the article had to discuss wound-related pain and focused on chronic wounds (i.e., PUs, leg ulcers, DFUs or MFWs). None of the articles met the criteria for inclusion as the studies related to acute wounds, burns, orthopaedics and some were animal studies. However, 12 articles were identified as providing supporting information for a number of important aspects of the assessment and management of wound-related pain. These included reported use of specific dressings (n=9) and the use of a topical steroid (in crushed tablet form) for the management of peristomal pyoderma gangrenosum (n=1). One review and one experimental study explored the pathophysiology of pain to examine the role of toll-like receptors (TLRs) and toxic by-products of bacterial lysis. A summary of the main characteristics of these articles are included as supplementary information in Appendix 7.

In relation to this chapter which examines physical therapies for pain management, including the impact of procedural-related pain, there is evidence that highlights the impact of dressing adhesion on pain intensity¹³⁷ which supports the need for choosing dressings that will minimise pain on removal¹³⁸. There are also a series of articles examining the role of polymeric membrane dressings (PMD) and the effect on pain associated with antinociceptive actions, modulation of inflammation, and mechanical and thermal hyperalgesia.¹³⁹ The ability to control oedema and by association, pain, has been evidenced in several published articles.^{140,141} Hegarty and Wong¹¹⁴ examined the use of a PMD in 23 patients with a radiotherapy-induced skin reaction. Patients reported positive outcomes in relation to pain, exudate control and comfort. In addition, an RCT conducted on partial thickness burns and split thickness skin grafts,¹⁴² demonstrated a statistically significant reduction in wound pain ($p < 0.01$) and increases in patient comfort ($p < 0.01$) when compared to the standard of care.

Several studies examined the role of foam dressings in patients with leg ulcers and PUs and reported positive

outcomes with regard to no pain being experienced whilst the dressing was *in situ* or at dressing change/removal.^{143,115,113,144}

The case series examining the use of crushed oral prednisolone tablet mixed with Stomahesive Protective Powder for the management of pain associated with peristomal pyoderma gangrenosum¹⁴⁵ presents a novel use of a medication to treat a relatively rare presentation*.

***Note: Inclusion of this evidence in this chapter does not infer any recommendation as it is an off-licence use but it does highlight that in some circumstances, particularly for unusual wounds more research on other potential interventions is needed.**

4.11 Summary of evidence

Evidence to support the role of physical therapies to manage wound-related pain incorporates physical exercise, as well as the importance of considering anticipatory pain where topical analgesics may be useful, and procedural-related pain (associated with wound debridement and dressings changes) where other approaches may need to be considered.

Regarding the role of physical exercise and wound-related pain the topic has been studied mostly in individuals with VLU. Furthermore, the primary outcomes of the evidence reviewed was wound healing and/or QoL rather than wound-related pain management specifically. Nevertheless, pain was considered as a secondary outcome or as an important category of the QoL measurement tools. According to the available evidence, there is only low-quality support for the use of physical exercise as an approach to the management of wound-related pain. Although an important finding was that physical therapy did not increase pain during or after exercise when patients were asked to increase their level of daily activity. Therefore, a recommendation would be to encourage individuals with VLU to exercise, particularly as venous insufficiency is associated with oedema, which in turn can cause discomfort (heaviness in the legs) and pain.

Some of the evidence reviewed highlighted the need for clinicians to consider procedural-related pain, particularly in relation to the use of debridement. Wound-related pain may occur during debridement procedures and can be treated systemically using oral analgesics, as well as the use of topical analgesics and local anaesthetics both during and after a debridement procedure or when dressing

changes are painful. According to the systematic reviews of Purcell et al⁵⁵ and Costa Ferreira et al⁵⁶ there was a significant reduction in procedural pain (dressing changes and debridement) when using dressings with ibuprofen and with the use of prilocaine/lidocaine as local anaesthetics. Therefore, these products might have also had a positive effect in the treatment of chronic wound-related pain, however, evidence is still scarce and inconsistent.

There is a need for methodologically high-quality investigations focusing on pain management in chronic wounds and pain assessment. As part of this further research, information on the setting, clinically relevant outcomes related to pain and larger sample sizes would enhance the strength of the evidence. Based on the existing evidence, we could conclude that there is evidence to support the use of ibuprofen impregnated foam dressings and local anaesthetics in reducing wound-related pain regarding procedural pain related to debridement and dressing changes.

In relation to the management of exudate there were inferences from the evidence that maintaining moisture balance is an important consideration for dressing choice as maceration could exacerbate the experience of pain as could the presence of peri-wound dermatitis. Similarly, the evidence reviewed highlights the importance of recognising and treating wound infection promptly, as pain is both a potential sign of infection and the experience of pain can be worsened by the presence of a wound infection. However, one of the challenges of drawing any specific conclusions is that many of the studies did not include pain management as primary outcome, pain was considered as one of the symptoms in the infected wounds.

The evidence to support LFU suggests that it may be useful debridement technique. More specifically neither technique led to an increase in the reported level of pain and from the patients' perspective the therapy was tolerable. Our recommendation is not that UAD and LFU should be considered as a treatment for pain, but in terms of procedural-related pain, and by association, wound-related pain this approach could be utilised by appropriately trained clinicians.

ESWT has been used as debridement method in several studies, one of the findings was that no additional pain treatment was required during the procedure. Additionally,

the therapy has a positive effect on wound healing and has anti-inflammatory effects which the evidence suggests improves blood flow perfusion and angiogenesis, as well as helping to reduce the presence of necrotic tissue. Indirectly it can be seen how these effects could impact on wound-related pain.

Evidence for the management of MFW wounds indicated that positive results in the treatment of pain was observed with the use of lidocaine/prilocaine 2.5% and morphine gel 0.2% as analgesics. In relation to antimicrobials and antiseptics the research showed that metronidazole 0.8%, polyhexamethylene biguanide (PHMB) with betadine 0.1% solution, octenidine solution, honey and silver have been used. Also, the use of non-adherent dressings covered with ibuprofen or dressings with opioids, had positive results in the studies of the effect in pain management locally, though further studies were required on different types of opioids. Topical therapies aimed at non-traumatic dressing changes and avoiding microtrauma if the dressing had adhered to the wound bed were discussed. Also, a combination of topical therapies used to reduce exudation and adhesion to wound bed in dressing changes were considered as pain management for this particular group of patients.

We acknowledge that we have not conducted a systematic review, therefore it was not possible to present a GRADE EtD framework¹¹⁶ which is a systematic and transparent approach to making well informed healthcare choices.¹¹⁶ Nevertheless, the recommendations are summarised from the best available evidence for clinical practice, as well as from clinical experience and expertise.

4.12 Summary of recommendations

A summary of recommendations for this topic is provided in Table 9.

Table 9: Summary of recommendations for physical therapies for individuals with wound-related wound pain

| Area of care and interventions | Process – timing and duration of intervention | Method of pain measurement of pain | Timing of pain evaluation condition) | Methods of evaluating the effectiveness of physical activity (once a week, or when there is a sudden change in the patient's) | competent (qualified) person |
|-------------------------------------|---|---|--|---|---|
| Physical activity/exercise – active | <p>Based on the patient actual status (vital sign measurement, Activity of Daily Living Test and Instrumental Activity of Daily Living Test) and on physicians' assessments</p> <p>Minimum of 15 minutes of physical activity per day by Nordic walking, spinning on a bicycle (sitting exercise is possible for patients with arthrosis of large joints, gait disorders, dizziness e.g., heel raises, tiptoe exercise)</p> | <p>Visual Analogue Scale (VAS) Numeric Rating Scale (NRS)</p> <p>Pain diary evaluation Mc Gill Pain Questionnaire</p> | <p>Always before the physical exercise and 15 minutes after</p> <p>Once a week, or when there is a change in therapeutic intervention and a change in physical condition</p> | <p>Objective: Activity of Daily Living test Instrumental Activity of Daily Living test Gait test Timed-up and go test Muscle Strength Testing Scale Physiotherapist examination</p> <p>Subjective: Interview, Observation</p> | <p>Physician – Comprehensive assessment of the patient's condition and determination of the extent of the physical load Physiotherapist/Occupational Therapist – suggesting appropriate physical activities and exercises General Nurse – assisting and supporting the patient in appropriate physical activities and exercise, assessing the intensity of pain and the patient's overall response to physical exertion and activity, assessing the patient's emotional state in relation to physical activity Tissue viability nurse – in collaboration with the general nurse, assess the impact of physical activity on the wound healing process (exudation, pain, wound area, wound base) Nutritionist – assessment of the patient's general condition, caloric intake needs and determination of appropriate diet and nutritional measures In patients with DFU a podiatrist should be involved</p> |

| | | | | | |
|---|---|---|---|---|--|
| <p>Physical activity/ passive (bedridden wheelchair-bound patients, unconscious patients)</p> | <p>Based on the patient actual status (vital sign measurement, Activity of daily living test) and on physicians/physiotherapist assessment At least 5–10 minutes of passive physical activity using the body part (limb) with the wound (heel-raises, tip-toe exercise) the possibility of lymphotherapy – if indicated and recommended possibility of using Basal Stimulation and Reflex Massage in cooperation with a physiotherapist possibility of using physical therapy (application of heat, cold) also in cooperation with a physiotherapist</p> | <p>Visual Analogue Scale (VAS) Numeric Rating Scale (NRS) Wong-Baker Faces Pain Rating Scale also referred to as the Faces Rating Scale. The Face, Legs, Activity, Cry, Consolability scale (FLACC) is a measurement used to assess pain for children between the ages of 2 months and 7 years or individuals that are unable to communicate their pain</p> | <p>Always before the physical exercise and 15 minutes after</p> | <p>Objective: Activity of Daily Living Test Muscle Strength Testing Scale Physiotherapist examination Subjective: Interview, observation</p> | <p>Comprehensive assessment of the patient's condition and determination of the extent of the physical load Physiotherapist/Occupational Therapist – suggesting appropriate physical activities and exercises General Nurse – assisting and supporting the patient in appropriate physical activities and exercise, assessing the intensity of pain and the patient's overall response to physical exertion and activity, assessing the patient's emotional state in relation to physical activity Tissue viability nurse) – in collaboration with the general nurse, assess the impact of physical activity on the wound healing process (exudation, pain, wound area, wound base) Nutritionist – assessment of the patient's general condition, caloric intake needs and determination of appropriate diet and nutritional measures In patients with DFU a podiatrist / foot care specialist should be involved</p> |
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|-------------|---|---|--|--|---|
| Positioning | <p>Based on RN assessment and objective risk assessment</p> <p>Manual handling or auto-tilting bed</p> <p>Appropriate positioning is important not only of the whole body and relieving pressure on at-risk areas, but positioning the body part (limb) with the wound is also essential for pain management to stimulate exudate drainage, reduce swelling, and relieve pressure and friction in the wound/cover/bandage area.) (including proper bandaging limbs where appropriate)</p> | <p>Visual Analogue Scale (VAS)</p> <p>Numeric Rating Scale (NRS)</p> <p>Wong – Baker Faces Pain Rating Scale</p> <p>also referred to as the Faces Rating Scale.</p> <p>The Face, Legs, Activity, Cry, Consolability Scale (FLACC)</p> | <p>Always before the physical exercise and every 15 minutes after for one hour (just for ICU and children)</p> | <p>Objective:</p> <p>Activity of Daily Living Test</p> <p>Muscle Strength Testing Scale</p> <p>Physiotherapist examination</p> <p>SSKIN strategy and Head to Toe skin inspection</p> <p>Subjective:</p> <p>Interview, observation,</p> | <p>General Nurse – assessment of the patient’s general condition, risk factors for decubitus and other complications (objective scales) determination of the positioning regime in accordance with the guidelines</p> <p>Physiotherapist/Occupational Therapist – suggesting appropriate positioning aids if needed</p> <p>Tissue viability nurse – in collaboration with the general nurse, assess the impact of positioning on the wound healing process (exudation, pain, wound area, wound base)</p> <p>Nutritionist – assessment of the patient’s general condition, caloric intake needs and determination of appropriate diet and nutritional measures</p> |
|-------------|---|---|--|--|---|

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| <p>Topical analgesics application (related to the intervention – debridement/re-dressing)</p> | <p>Based on a comprehensive assessment of the patient with procedural pain related to the intervention – debridement, wound re-dressing or with prolonged pain between wound dressings (patient's history, information from medical records, information from the accompanying person)</p> <p>The possible effective topical analgesics suitable for the procedural pain management are lidocaine/prilocaine 2.5% and morphine gel 0.2%</p> <p>For the patients with prolonged pain between wound dressings metronidazole 0.8%, polyhexamethylene biguanide (PHMB) with betadine 0.1% solution, octenidine solution, honey and silver have been used as well as (foam) dressings with ibuprofen (dose of 0.5mg/cm2) or opioids and anti-adherent dressing</p> | <p>Visual Analogue Scale (VAS) Numeric Rating Scale (NRS)</p> | <p>Always before the procedure (debridement, redressing) and 15 minutes after</p> | <p>Objective (before and after the intervention): Activity of Daily Living Test Muscle Strength Testing Scale Physiotherapist examination SSKIN strategy and Head to Toe skin inspection Subjective: Interview, observation</p> | <p>Physician – Comprehensive assessment of the patient's condition and determination of the drugs/medications (topical agents, ointments, special dressings/coverers) to be applied General Nurse – assisting and supporting the patient in expression of their previous experiences, checking the patient records for the information, applying medication based on the prescription Tissue viability nurse – in collaboration with the general nurse, assess the impact of local/topical treatment on the wound healing process (pain, level of patient's collaboration, exudation, pain, wound area, wound base)</p> |
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5.

Role of patient education for wound-related pain

5.1 Introduction

This chapter reviews evidence related to the role of patient education for wound-related pain management and chronic wounds. The results are based on five systematic reviews, supplemented by seven individual studies identified from the reviews. A summary of recommendations from the evidence, clinical experience and expertise is provided at the end of the chapter to facilitate implementation into clinical practice.

5.2 Method

5.2.1 Search method

The search strategy aimed to find systematic reviews related to the role of patient education in the holistic management of wound related pain. We searched the L OVE platform, which collects systematic reviews retrieved from the systematic reviews database Epistemonikos⁷ and allocates them to specific L OVEs and questions.⁸ We conducted a search in L OVE Wounds and burns on 17 June 2022 and retrieved relevant systematic reviews using the filter for 'behavioural' interventions. There were no language, publication year or publication status restrictions.

We screened the reference lists of all eligible systematic reviews and hand searched websites of relevant organisations and institutions.

5.2.2 Inclusion criteria

Systematic reviews of pain and chronic wounds which discussed an intervention related to pain and patient education.

5.2.3 Exclusion criteria

Acute wounds, burns (burn injuries)

5.2.4 Selection of studies

Retrieved titles and abstracts were exported into Rayyan⁵² by an information specialist (Simona Slezáková). The title and abstracts were screened in duplicate and independently by two authors (Andrea Pokorná, Samantha Holloway). The blind mode within Rayyan was kept on until both authors had completed the first screening. Subsequently the blind

mode was turned off to allow the authors to view each other's decisions. The authors then met to resolve the disagreements and agree which results would move to the second stage of full-text review of selected articles. Full text-screening was conducted similarly to the title and abstract screening. Following the full-text screening a list of studies for inclusion / exclusion was created.

The original search yielded 112 results. Following the title and abstract screening 96 were excluded, the main reason for exclusion being that they were acute wounds (burns, surgical). This generated 16 articles for full text review, from which we screened 15, as one full text was not available. Ten full texts were excluded as they did not have the relevant outcome or population. Of the remaining number, five articles met the inclusion criteria and were included in the analysis. From these five systematic reviews, seven individual studies were identified and included as part of the analyses (Appendices 8 and 9 respectively). The screening and the assessment process is described in detail in flow diagram (Figure 10).

5.2.5 Data extraction

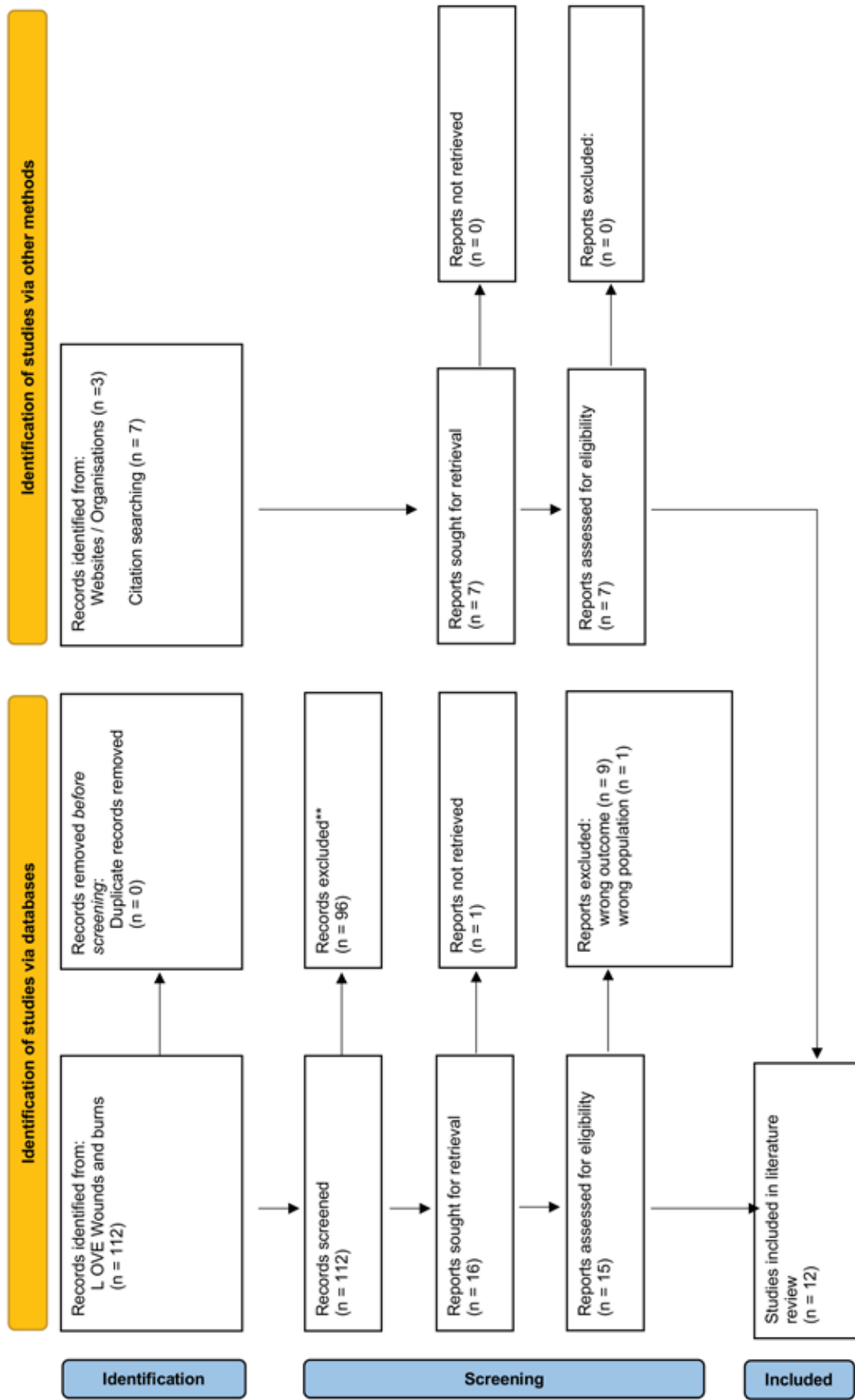
Relevant data were extracted from the included reviews by Samantha Holloway.

5.3 Results

5.3.1 Characteristics of the systematic reviews

The five systematic reviews included a total of 66 studies. The number of studies included ranged from three to 31 and the date range for the database search was from 1995–2021 across all the reviews. The total sample size derived from the reviews was 10,499 patients and 144 health/social care professionals. One study¹⁴⁶ did not provide clear information on the number of participants in the seven studies each reviewed. The studies included in the reviews were conducted predominantly in the UK, USA and Australia, with fewer in Sweden, Germany, New Zealand, Brazil, Canada, Denmark, Netherlands, Iran, Morocco, Switzerland, China, Ireland, France, India and South Korea. One study¹⁴⁷ did not collate the information by geographical location. Three of the reviews^{146,147,148}

Figure 10: Flow diagram of the screening and the assessment process for role of patient education (modified PRISMA 2020 flow diagram)



focused on participants with leg ulcers (venous, chronic), one review examined all types of chronic wounds (DFU, VLU, PU)¹⁴⁹ and one investigated PUs.¹⁵⁰ The aims of the reviews were heterogenous, so it was not possible to pool the data across the evidence.

5.3.2 Leg ulcers

Two studies^{147,148} examined reasons or determinants of non-adherence to prescribed compression therapy. Van Hecke et al¹⁴⁷ identified that pain, discomfort and a lack of valid lifestyle advice by healthcare professionals (including conflicting advice, no specific advice or impossibility of instructions) were identified as primary reasons for non-adherence. Van Hecke and colleagues concluded that a pain management programme was recommended, although no further information was provided on what such a programme might include. The BPS¹⁵¹ produced guidelines for pain management programmes (PMPs), this is currently undergoing a review and update. Both Van Hecke et al¹⁴⁷ and Weller et al¹⁴⁸ also noted that communication with the patient's GP is required to ensure provision of analgesia. Importantly, and in relation to the use of compression therapy specifically, Van Hecke et al and Weller et al highlighted that it's important for nurses (*sic*) to inform the patient that their pain levels may increase during the first few weeks of therapy, therefore it may be helpful to take regular analgesia. Provision of 'coping instructions' was mentioned but not elaborated on.

Weller et al¹⁴⁸ reviewed the benefits and harms of interventions to help people adhere to compression therapy for VLU. One of the outcomes of the review included pain. Of the three studies cited, one (Edwards et al, 2009) examined the effectiveness of a community nursing intervention on QoL and wound healing in patients with chronic leg ulcers. The intervention included attendance at a weekly leg club with peer support, goal setting and social interaction plus standard care which was compared to standard care alone. Pain was also one of the secondary outcomes in the study and was assessed using the RAND instrument and SF-36 at 12 weeks and the Medical Outcomes Study Pain Measure at 24 weeks (on a 100-point continuous scale) (Box 3). The data for the 24-week follow-up showed that there may be a small decrease in pain intensity in the participants attending the Leg Club compared with the home visit care group (overall total pain score, $Z=2.71$, $p=0.003$). The Leg Club referred to in the study is based on the Lindsay Leg Club Model (LLCM)¹⁵² which is said to

provide an environment where members (*sic*) can access education, advice and information, however Edwards et al's (2009) study does not mention providing education or advice specifically.

The finding that a LLCM may have a positive impact on pain is supported in a review by Liberato et al¹⁴⁶ who examined nursing interventions used for the management of pain in people with venous ulcers. Liberato and colleagues reviewed an earlier study by Edwards et al (2005) which was an RCT to determine the effectiveness of a community nursing intervention (a Leg Club) on pain and healing. Edwards et al reported significant improvements in levels of pain and ulcer healing in the intervention group receiving the '*new model of care*'. Similarly, the study undertaken in 2005 (Edwards et al. 2005) fails to mention whether specific guidance or advice was provided. More recently Gethin et al¹⁴⁹ (undertook a review of evidence for person-centred care in chronic wound care. One of the themes that emerged was *Patient Education* and as part of this Gethin and colleagues¹⁴⁹ discussed the later study by Edwards et al (2009) arguing that it supports the positive impact that the LLCM of care can have on patient education and reduction of pain.

Taken together these three reviews suggest that provision of care based on the LLCM can have a positive impact on pain, however whether this is related to the provision of patient education and advice in a Leg Club specifically is not clear and would require further exploration.

Box 3: References for evaluation instruments for QoL and pain measurement

SF-36

Brazier, J.E., Harper, N.M., Jones, A., O'Cathain, K.J., Thomas, T., Usherwood, T. & Westlake, L. (1992). Validating the SF-36 health questionnaire: A new outcome measure for primary care. *BMJ*, 305:160

Also available here: <https://nexusipe.org/advancing/assessment-evaluation/short-form-sf-36-health-survey>

Medical Outcomes Study

<https://jamanetwork.com/journals/jama/article-abstract/378368>

Gethin et al¹⁴⁹ included a study by Kelechi et al (2014) in their systematic review. Kelechi et al reported on the effect of a nurse-directed intervention to reduce pain and improve behavioural and physical outcomes in patients with

critically colonised/infected chronic leg ulcers (n=21). The intervention, Motivational enhancement and conditioning activity for leg function (MECALF) was compared to conditioning activities for lower leg function (CALF) alone. Outcomes included, pain, motivation, self-efficacy, physical activity, leg strength, and range of motion. The intervention was a six week motivational enhancement programme, including patient education, and a conditioning activity for leg function, plus two additional visits in weeks 6–8 without active motivational enhancement. The control group completed conditioning activities along with a handout at baseline and weekly visits. The results showed that overall pain was statistically significantly reduced ($p=0.046$) in both groups of patients with painful critically colonised/infected leg ulcers measured at week 8; two weeks after the study period. The CALF group experienced a slightly greater reduction in pain intensity than the MECALF group which suggests that exercise activities supported by written information and regular follow-up is an effective strategy with no requirement for additional motivational approaches. However, this was a small study (n=21), therefore it is difficult to generalise the findings too widely.

Gethin et al's¹⁴⁹ review also examined research by Tulleners et al (2019) who studied the impact of a new transdisciplinary specialist service supplemented with telehealth consultations offered to 29 patients with VLUs. Tulleners and colleagues examined patient experience and outcomes such as wound healing and QoL, including self-reported pain scores on a scale of 0–10.⁹⁰ All participants received a tailored dressing plan upon completion of their appointment, with directions on dressing type, application and exercises, if appropriate. The average QoL score based on a 0–1 scale with 1 representing the '*best health you can imagine*', increased from 0.69 to 0.84 ($p<0.001$) after three months; wound size decreased by 85.4%; and pain, reported using a 10-point scale, reduced from a mean of 6.35 to 4.74 ($p<0.001$). The inference from this study was that patient-centred care, listening to patient feedback and exploring reasons why they were unable to follow a suggested care plan is important. This finding supports the need for shared decision-making and concordance with goals of management, including consideration of pain, and in turn confirms the need for education to be part of a collaborative approach.

The notion of the importance of listening to patients was identified in a qualitative study by Green et al,¹⁵³ which

was included in Gethin et al's¹⁴⁹ systematic review. Green et al identified that during nurse-patient consultations opportunities to explore issues related to experience of living with leg ulceration were not always fully explored. Green and colleagues provided an example of a patient being unsure whether increased pain fell within the nurse's sphere of responsibility and instead discussing the pain with a doctor in a medical consultation. Equally if the patient perceives the nurse to be busy or in a hurry, they may not wish to hold them up. In the wider context of patient education and wound pain the implications of this study are that healthcare professionals need to demonstrate a willingness to listen and engage with the individual in order to facilitate a therapeutic relationship to address any issues they may have.¹⁵³ This conclusion is also reflected in the EWMA Document, Evidence for Person-Centred Care in Chronic Wound Care.⁵⁰

Overall, the findings from this set of evidence are applicable to individuals with chronic leg ulcers specifically.

5.3.3 Pressure ulcers (PUs)

The systematic review by Thomas et al¹⁵⁰ examined the effectiveness of structured patient education in individuals with PU. Thomas and colleagues studied the impact on knowledge, participation, wound healing, and QoL. Of the five studies cited in the review two reported that patient education had a positive effect on QoL: Carlson et al (2019) and Arora et al (2017). The concept of pain is reflected in both the QoL tools used by these authors (EQ-5D-5L [pain/discomfort] and SF-36 [pain]) therefore the studies were deemed relevant to this review.

Arora et al (2017) employed the use of pamphlets about PU prevention, weekly advice by telephone for 12 weeks, which included information on self-help strategies i.e. appropriate seating, bed overlays, cushions, equipment, diet, nutrition and wound dressings. In addition, they were advised about techniques to relieve pressure and when to seek further medical or nursing attention. Some participants were advised to remain on strict bed rest. Participants were also provided with continence advice. Each week, participants and the health-care professionals negotiated goals that were reviewed at the next phone call.

Carlson et al's (2019) intervention included a Pressure Ulcer Prevention Programme (PUPP) which included six modules

(Table 10). Module 5 (Happiness and Personal Well-Being) included an element related to managing pain.

The intervention group received a structured approach to the delivery of the PUPP module content. This was supported with a combination of in-home visits and phone contact. Communication was provided in English or Spanish (based

in patient preference). Occupational Therapists delivered the intervention and liaised with Registered Nurses if wound care issues arose. The PUPP included an ‘intensive phase’ (months 1–6) and a ‘tapered phase’ (months 7–12). During the intensive phase pre-planned weekly contact included individual, face-to-face home sessions (n=9) and telephone calls (n=15). The majority of the content of each module

Table 10: Pressure Ulcer Prevention Programme (PUPP) – modules overview (reproduced from Carlson et al. 2019) (154)

| Modules | Fixed Elements | Variable (Optional) elements |
|---|---|--|
| Module 1 – Understanding Lifestyle and Pressure Ulcer Risk | Importance of lifestyle Prevention Practices in daily life Personal Risk Profile Development of personal prevention plan | Activity versus health; life events; exercise; nutrition and weight; smoking; alcohol/substance abuse; prevention techniques; pressure reliefs; pressure and shearing; stages of pressure ulcers; response to emerging pressure ulcers |
| Module 2 – Advocacy | Attendant Care Partnering with your health-care professional Self-advocacy Fine-tuning of personal prevention plan | Access to health care; medical treatments; medical administration issues; medical complications; selecting/managing care attendants; emotions; attitudes and self-efficacy; decision making |
| Module 3 – Equipment and the Physical Environment | Equipment Transportation and use of environmental options Further refinement of Personal Prevention Plan | Personally relevant transportation options; overcoming environmental barriers; detail on specific equipment options; living situations; safety in and outside the home |
| Module 4 – Social Support | Social Support Family and Intimate Relationships Review of current use of personal prevention plan | Developing friendships; social networking; e-mailing; dealing with family problems; job issues; social contact and pressure ulcer risk; overcoming loneliness |
| Module 5 – Happiness and Personal Well-Being | Accomplishing a sense of well-being Relation of mental health to pressure ulcer risk Further refinement of Personal Prevention Plan | Coping strategies; managing pain ; depression; stress; risk taking; alcohol and drugs; healthy activity; maintaining a positive outlook |
| Module 6 – Planning the Future | Successfully anticipating change Making healthy habits permanent Review of Personal Prevention Plan | Aging skin; finances; strategizing for continued success; personal organization skills; aging and spinal cord injury |

was delivered in the intensive phase. During the tapered phase, contact was twice per week and included in-person one on one home visits (n=2) and telephone calls (n=9). Contacts in the tapered phase centred on review of prevention practices, reinforcement of personalised lifestyle applications, and responses to developing risk situations. Throughout the intervention, face-to-face sessions lasted on average 1.5 hours, and phone call duration averaged 30 minutes. Carlson et al (2019) sought to determine the impact of the PUPP intervention on PU incidence specifically and showed that rates did not differ between the intervention and control group. With regards to changes in QoL and in particular the difference in pain at baseline and at 12 months there was no statistically difference in the intervention versus the control group.

Thomas et al¹⁵⁰ deemed the two studies to be of high methodological quality and suggested that the findings support the effectiveness of structured patient education for individuals with a spinal cord injury and PI in improving QoL. However, the implications for provision of patient education related to pain and wounds is unclear.

5.4 Summary of recommendations based on the evidence

Based on a careful analysis of available resources and our current scientific and clinical experience, we have presented a summary of recommendations for wound and pain patient education in Table 11. Pain is unfortunately a common part of life for persons with non-healing wounds, yet the field of pain management is still under-researched scientifically and recommendations for patient education are lacking. It should be borne in mind that individuals with different types of wounds experience different types of pain in terms of duration, characteristic features and nature of influencing factors. In the Evidence Framework Summary presented we have attempted to identify the most important areas for education, along with listing appropriate educational tools and indicating competent professionals to implement education. Through this Evidence Framework we are focusing on empowering practitioners to drive change through engaging them equitably in the design, production, and use of evidence. At the core of the framework's theory of change is a belief, that by prioritizing the learning and decision-making needs of practitioners, and by working collaboratively with practitioners to build timely evidence, we will see more effective programs, policies, and practices

with evidence of equitable outcomes for patients, their families, and all other stakeholders. We acknowledge that we have not conducted a systematic review, therefore it was not possible to present a GRADE EtD framework,¹¹⁶ which is a systematic and transparent approach to making well informed healthcare choices. Nevertheless, the recommendations are summarised on the best available evidence for clinical practice, as well as clinical experience and expertise.

Table 11: Summary of recommendations for patient education

| Area of education | Timing and duration of education | Method of the education/form of education | Repetition | Method of evaluating the effectiveness of education | Competent (qualified) person and main education content |
|---|---|---|---|--|--|
| Aetiology of the wound + symptomatology causes of pain | when care is initiated/terminated by a particular care provider at least for 30 minutes for the first session | Interview Educational pamphlet/leaflet Online educational materials (The introductory part could be in the group session) afterward individual education | Yes, based on the evaluation of the knowledge level | Simple face to face or phone call Interview; Interview with short poll Online short poll | Physician – introduction about the disease, pathophysiology of the disease and pain Nurse (tissue viability nurse) |
| Nonpharmacological methods of pain relief | when care is initiated by a particular care provider | Interview, practicing the method – training | Yes, based on the evaluation of the knowledge level | Interview, Observation, Pain diary evaluation, physiotherapist examination | Nurse (tissue viability nurse) Physiotherapist/ Occupational Therapist Psychotherapeutist, Nutritionist |
| Pharmacological methods of pain relief | when care is initiated by a particular care provider | Interview, practicing the method – training (individual education with possible attendance of lay carers) | Yes, based on the evaluation of the knowledge level | Interview, Observation, Pain diary evaluation, blood tests, | Physician – Algesiologist, Nurse practitioner (if available in particular healthcare system), Pharmacologist, |
| Methods for assessing pain relief | when care is initiated by a particular care provider | Interview Educational pamphlet/leaflet Online educational materials (individual education with possible attendance of lay carers) | Yes, based on the evaluation of the knowledge level | Interview, Observation, Pain diary evaluation, physiotherapist examination | Nurse (tissue viability nurse) Physiotherapist/ Occupational Therapist Psychotherapeutist, Nutritionist |
| Methods for assessing the impact of pain on quality of life | when care is initiated by a particular care provider | Interview Educational pamphlet/leaflet Online educational materials (individual education with possible attendance of lay carers, for special type of wounds the group education would be beneficial) | Yes, based on the evaluation of the knowledge level | Tools for HRQoL assessment including pain domain, Interview, focus group meetings | Physician – Psychologist Nurse (tissue viability nurse) Psychotherapeutist/ Psychotherapeutist, Social worker |

6. Role of psychological approaches for wound-related pain

6.1 Introduction

This chapter reviews evidence related to the role of psychological therapies for wound-related pain management and chronic wounds. The results are based on two systematic reviews. A summary of recommendations from the evidence, clinical experience and expertise is provided at the end of the chapter to facilitate implementation into clinical practice.

6.2 Method

6.2.1 Search method

The search strategy aimed to find systematic reviews related to the role of psychological approaches in the holistic management of wound related pain. We searched the L OVE platform, which collects systematic reviews retrieved from the systematic reviews database Epistemonikos⁷ and allocates them to specific L OVEs and questions.⁸ We conducted a search in L OVE Wounds and burns on 17 June 2022 and retrieved relevant systematic reviews using the filter for 'behavioural' interventions. There were no language, publication year or publication status restrictions.

We screened the reference lists of all eligible systematic reviews and hand searched websites of relevant organisations and institutions.

6.2.2 Inclusion criteria

Systematic reviews of pain and chronic wounds, which discussed an intervention related to management of wound-related pain were included.

6.2.3 Exclusion criteria

Acute wounds, burns (burn injuries).

6.2.4 Selection of studies

Retrieved titles and abstracts were exported into Rayyan⁵² by an information specialist (Simona Slezáková). The title and abstracts were screened in duplicate and independently by two authors (Alisha Oropallo, Andrea Pokorná). The blind mode within Rayyan was kept on until both authors had completed the first screening. Subsequently the blind mode was turned off to allow the authors to view each other's decisions. The authors then met to resolve the

disagreements and agree which results would move to the second stage of full-text review of selected articles. Full text-screening was conducted similarly to the title and abstract screening. Following the full-text screening a list of studies for inclusion/exclusion was created.

The original search yielded 112 results. Following the title and abstract screening 100 were excluded, the main reasons for exclusion being wrong outcome or population. This generated 12 articles for full text review. Ten full texts were excluded as they did not have the relevant outcome or population (nine of them were focused on patients with burn injuries and one of them specifically on children with burns injuries). Two articles met the inclusion criteria and were included in the analysis (Appendix 10). The screening and the assessment process is described in detail in flow diagram (Figure 11).

6.2.5 Data extraction

Relevant data were extracted from the included reviews by Samantha Holloway.

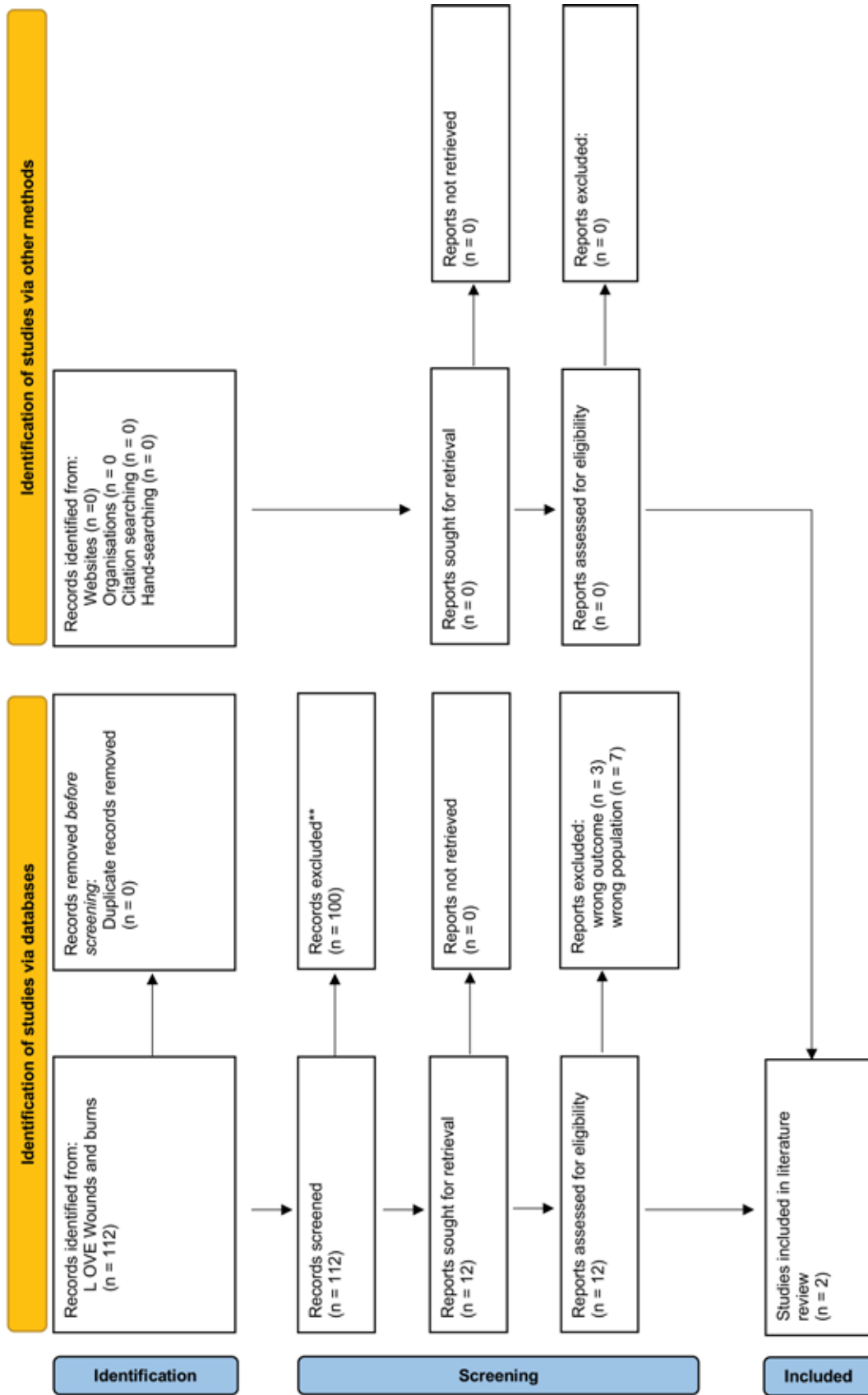
6.3 Results

6.3.1 Characteristics of the systematic reviews

The characteristics of the two reviews^{146,149} have already been discussed in Chapter 5 on patient education.

Liberato and colleagues¹⁴⁶ reviewed nursing interventions used in the management of pain in people with VLU. Of relevance to the psychological aspects of managing pain was the study by Kane et al¹⁵⁵ which examined the use of aromatherapy and music therapy as strategies to manage pain during dressing changes. This study will be discussed in more detail in the next chapter which reviews complementary and alternative therapies, however, in relation to psychological aspects the results of the study point to the applicability of these therapies as potential distraction/relaxation techniques² (Table 13). Liberato et al¹⁴⁶ also discussed the positive impact that social models of care for individuals with chronic venous ulcers (such as Leg Clubs) can have in terms of social support. It could also be that attendance at a Leg Club impacts on the attention, cognition and emotion domains proposed

Figure 11: Flow diagram of the screening and the assessment process for psychological approaches (modified PRISMA 2020 flow diagram)



by Linton and Shaw², although further research examining these specific aspects would be needed to explore this.

Gethin et al¹⁴⁹ also reviewed the role of Leg Clubs and cited a study by Finlayson et al (2010). The intervention included weekly Leg Club visits, peer support, goal setting and social interaction promotion. The results showed an increase in QoL including activities of daily living, morale and self-esteem. Wound healing (ulcer area reduction) and pain reduction were also reported. In relation to Linton and Shaw's ² work these findings speak to Leg Clubs having a positive effect on a number of factors (attention, cognition and emotion) to counteract the possible effects on pain and disability.

Gethin et al¹⁴⁹ discussed a study by Kelechi et al (2014) (reviewed in Chapter 5) which reported on the positive

outcomes of a motivational enhancement programme for individuals with infected leg ulcers. Based on these results it would appear that such a programme may help to address negative cognition (cognitive restructuring) and emotion/emotion regulation activation, thereby promoting well-being). This literature search found no evidence on psychological approaches to managing wound-related pain, such as Acceptance Commitment Therapy (ACT) or Cognitive Behavioural Therapy (CBT) that are currently used in the management of chronic pain.¹⁵⁶ Table 12 summarises the psychological factors associated with pain, their processes and additionally treatment strategies that may be suitable for individuals living with chronic wound-related pain.

Figure 12 presents nociception, pain perception, and the biobehavioural response to pain, in the nociceptive pathway

Table 12: Psychological factors in pain, their processes and management strategies²

| Factor | Description | Possible effect on pain and disability | Treatment strategy |
|--|---|--|--|
| Attention | Pain demands our attention | <ul style="list-style-type: none"> • Vigilance may increase pain intensity • Distraction may decrease pain intensity | <ul style="list-style-type: none"> • Distraction techniques • Interceptive exposure |
| Cognition | How we think about our pain may influence it | <ul style="list-style-type: none"> • Interpretations and beliefs may increase pain and disability • Catastrophising may increase pain • Negative thoughts and beliefs may increase pain and disability • Expectations may influence pain and disability • Cognitive sets may reduce flexibility in dealing with pain and disability | <ul style="list-style-type: none"> • Cognitive restructuring • Behavioural experiments are designed, for example, to disconfirm unrealistic expectations and catastrophising |
| Emotions and emotion regulation | Pain often generates negative feelings and these negative feelings may influence pain and fuel cognition, attention, and overt behaviours | <ul style="list-style-type: none"> • Fear may increase avoidance behaviour and disability • Anxiety may increase pain disability • Depression may increase pain disability • Distress, in general, fuels negative cognitions and pain disability • Positive emotions might decrease pain | <ul style="list-style-type: none"> • Cognitive-behavioural therapy programs for anxiety and depression • Activation (to increase positive emotion) • Relaxation • Positive psychology techniques that promote well-being and positive emotions |
| Overt behaviour | What we do to cope with our pain influences our perception | <ul style="list-style-type: none"> • Avoidance behaviour may increase disability • Unlimited activity (overactivity) may provoke pain • Pain behaviours communicate pain | <ul style="list-style-type: none"> • Operant, graded activity training • Exposure in vivo • Coping strategies training |

(adapted from Garland²¹) and where pain management strategies work.

6.4 Summary of recommendations

No specific conclusions from the limited body of evidence for psychological approaches could be elicited. However, some key themes emerged, for example the use of distraction and relaxation techniques to help with procedural-related pain was noted. The evidence also seemed to indicate a role for social models of care and specifically Leg Clubs in helping to manage pain. Based on these findings that such models have an indirect effect of reduction of pain

are likely to be related to the reported increases in QoL measures. These QoL measures include enhancing ability to undertake activities of daily living and improving self-esteem. There also seemed to be evidence that strategies to enhance motivation and patient activation are important. Approaches that promote an individual's well-being as well as helping to regulate emotions are essential.

The next chapter will examine the evidence for complementary and alternative approaches for wound-related pain.

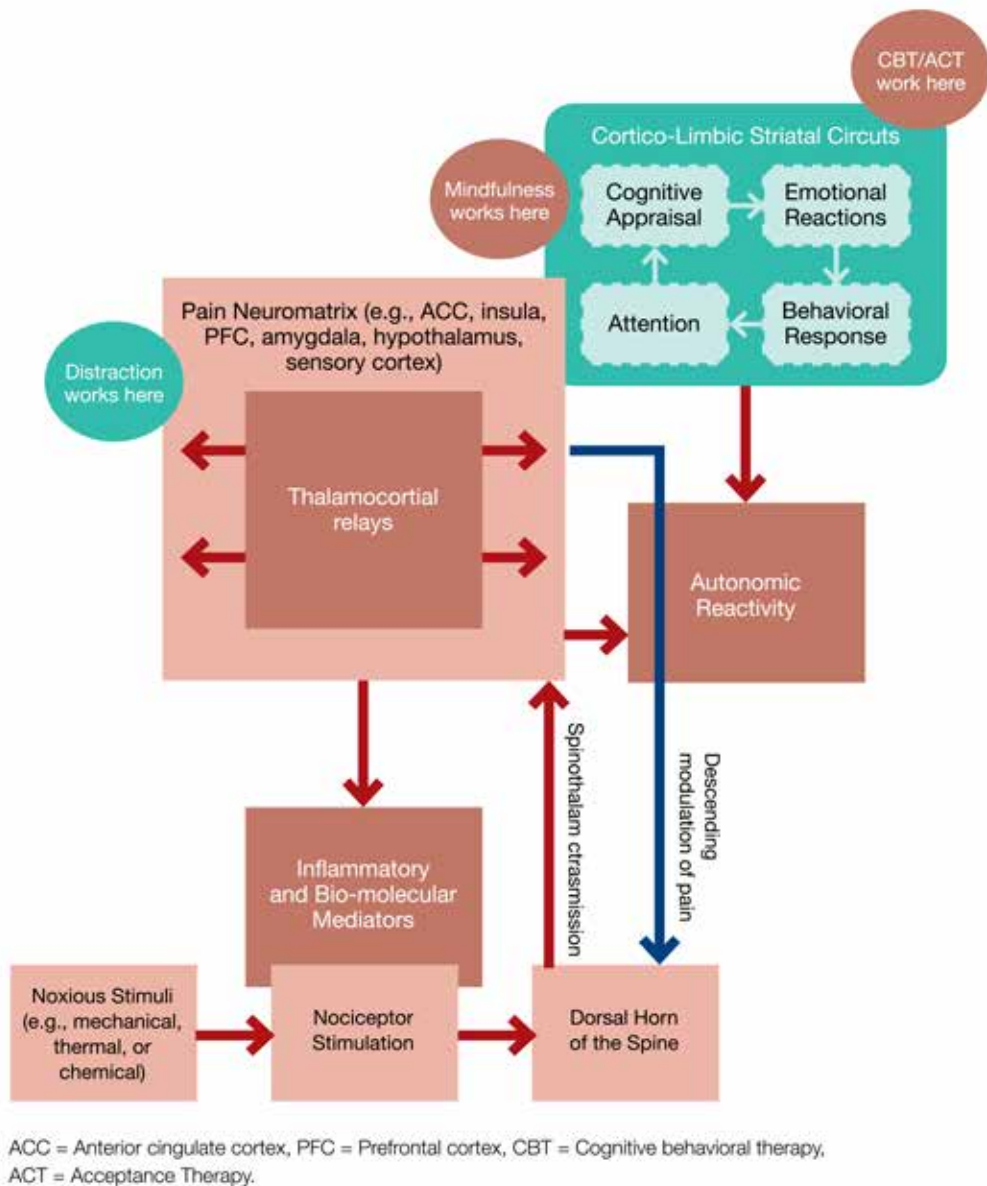


Figure 12: The nociceptive pathway, adapted from Garland (2012)²¹

7. Role of complementary and alternative medicine for wound-related pain

7.1 Introduction

This chapter reviews evidence related to the role of complementary and alternative therapies for wound-related pain management and chronic wounds. The search results for this theme identified reviews related to *honey*, *traditional Chinese medicine (TCM)*, *anthocleista*, *low-level laser therapy*, *Ficus Deltoidea Jack* and *interventions for MFWs*. The results are based on 18 systematic reviews. A summary of recommendations from the evidence, clinical experience and expertise is provided at the end of the chapter to facilitate implementation into clinical practice.

7.2 Method

7.2.1 Search method

The search strategy aimed to find systematic reviews related to the role of complementary and alternative medicine in the holistic management of wound-related pain. We searched the L OVE platform, which collects systematic reviews retrieved from the systematic reviews database Epistemonikos⁷ and allocates them to specific L OVEs and questions.⁸ We conducted a search in L OVE for *wounds* and *burns* on 17 June 2022, and retrieved relevant systematic reviews using the filter for *complementary and alternative medicine*. There were no language, publication year or publication status restrictions.

We screened the reference lists of all eligible systematic reviews and hand-searched websites of relevant organisations and institutions.

7.2.2 Inclusion criteria

Systematic reviews of pain and chronic wounds, which discussed an intervention related to pain and complementary and alternative medicine.

7.2.3 Exclusion criteria

Acute wounds, burns (burn injuries).

7.2.4 Selection of studies

Retrieved titles and abstracts were exported into Rayyan⁵² by an information specialist, Simona Slezáková. The title and abstracts were screened in duplicate and independently

by two authors (Kirsti Ahmajärvi, Samantha Holloway). The blind mode within Rayyan was kept on until both authors had completed the first screening. Subsequently, the blind mode was turned off to allow the authors to view each other's decisions. The authors then met to resolve the disagreements and agree which results would move to the second stage of a full-text review of selected articles. Full-text screening was conducted similarly to the title and abstract screening. Following the full-text screening a list of studies for inclusion / exclusion was created.

The original search yielded 158 results including one duplicate. Following the title and abstract screening 125 were excluded, the main reason for exclusion being that they were acute wounds (burns, surgical). This generated 32 articles for full text review. Of these 14 full texts were excluded as they did not have the relevant outcome/population or did not meet criteria for publication type. This left 18 articles that met the criteria and were included in the analysis (Appendix 11). The screening and assessment process is described in detail in the flow diagram (Figure 13).

7.2.5 Data extraction

Relevant data were extracted from the included reviews by Samantha Holloway.

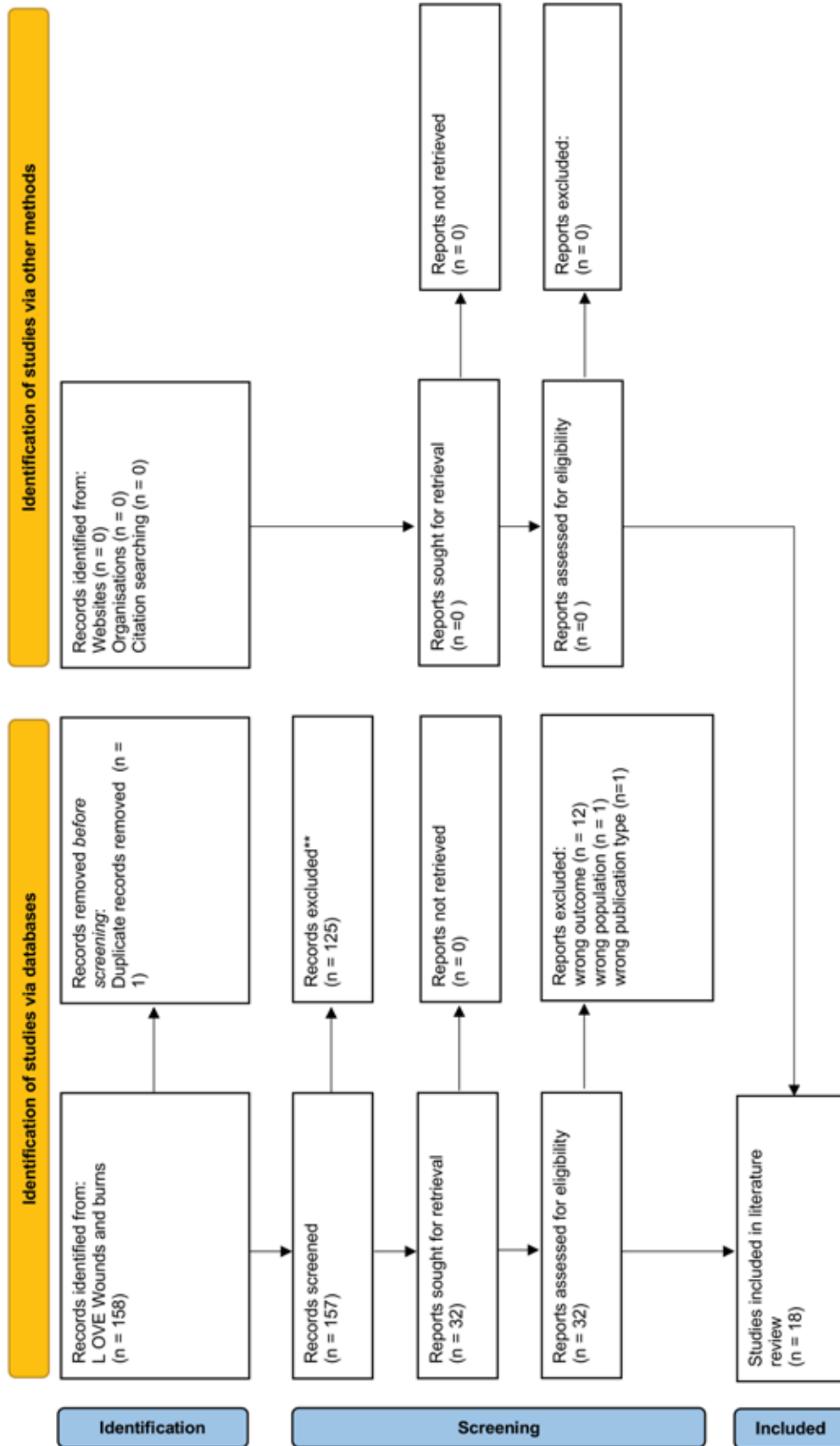
7.3 Results

7.3.1 Characteristics of the systematic reviews

A full-text review of 18 systematic reviews was undertaken; the topics of the reviews included honey (n=10), TCM (n=2), anthocleista (n=1), low-level laser (n=1), *Ficus Deltoidea Jack* (Moraceae) (n=1), interventions for MFWs (n=1) and two were generic reviews of any interventions for chronic wounds which included alleviation of pain.

Of the 18 systematic reviews, 11 provided a detailed PRISMA flow diagram to report the number of studies included. The total number of studies across these reviews was n=315, with n=133 focusing solely on the use of honey. The remaining seven reviews did not provide sufficient information to determine the number or type of studies; in fact, these were more of a narrative synthesis of the

Figure 13: Flow diagram of the screening and the assessment process for complementary and alternative medicine (modified PRISMA 2020 flow diagram)



evidence rather than true SRs. Thirteen reviews provided information about the date range or indicated a specific search date. The date range for the searches across these reviews was 1966–2019 for human/clinical studies and slightly more recent for *in vivo* and *in vitro* (animal) studies (2021). Five reviews did not provide information about the date range. Only seven of the 18 reviews provided information about the sample sizes of the studies included; the total number of participants was n=3392, and of these, more than half (n=1875) related to the use of honey.

Twelve of the reviews provided information about the geographical location of the studies. For the studies examining the use of honey, most continents were represented, with no predominance in one particular country (Box 4).

Box 4: Geographical location of studies related to honey

| | | | |
|-----------|--------------|----------------|----------|
| Africa | Netherlands | UK | Nigeria |
| Belgium | Egypt | Germany | Portugal |
| Qatar | New Zealand | Malaysia | Denmark |
| Greece | Saudi Arabia | India | Pakistan |
| Hong Kong | Indonesia | Czech Republic | China |

One review of the use of propolis focused on Polish research, and the reviews on generic interventions examined evidence from Canada, Denmark, Australia, and the UK. The review of *Ficus Deltoidea Jack* (Moraceae) focused on its use in Malaysia, and the use of TCM was based on studies in China.¹⁵⁷

The evidence will be presented in themes related to the interventions, beginning with the use of honey.

7.4 Honey

The earliest review reporting on the use of honey was by Fox¹⁵⁸ who reviewed evidence from individual and multiple case studies published between 1966–2002. Six studies were identified, providing a total of 66 patients with different wound types (recalcitrant surgical wounds, chronic wounds, ‘ulceration’, chronic infected wounds, leg ulceration and recalcitrant wounds and ulcers). Five of the studies examined the effect of honey on pain, with three reporting a decrease in pain. Very limited information was provided on the methodological quality of the studies;

in particular, it was difficult to determine how pain was assessed. The review sets the scene for the role of honey and its potential impact on pain but is relatively limited in terms of providing strong evidence.

A subsequent review by Mwipatayi et al¹⁵⁹ examined the evidence for the clinical effects of topical honey on chronic leg ulcers (CLU). Pain was not a primary outcome of the review; however, Mwipatayi and colleagues discussed pain as part of the theoretical framework for their review, highlighting the reported anti-inflammatory effects of honey. While the review title suggests the focus was on patients with CLU, of the total number of patients included (n=50), less than half (n=21) had chronic wounds. Mwipatayi et al discussed that all of the studies reviewed were at risk of different sources of bias (lack of blinding, poor reporting quality, and limited sample sizes). All of the studies were clinical, observational trials, and none reported on the effect of honey on wound-related pain.

Bardy et al¹⁶⁰ provided a synthesis of the evidence related to the role of honey in cancer care. The authors cited two studies which examined pain in patients with leg ulcers: Dunford and Hanano (2004) and Oluwatosin et al (2000). The multi-centre, non-randomised study by Dunford and Hanano (2004) included 40 patients, the results showed a statistically significant reduction in pain (1.6±1.22 to 1.08±1.54, p<0.001). However, in a non-randomised, comparative study Oluwatosin et al (2000) did not find any statistically significant reduction in pain at the end of treatment (p>.05).

Dunford and Hanano’s (2004) research is the most detailed account of the assessment of pain and the effect of honey identified as part of this current review; therefore, this study was reviewed in more detail. Dunford and Hanano used the McGill Pain Questionnaire to assess pain, where zero=no pain; 1=mild pain; 2=discomfort; 3=distressing pain; 4=horrible pain; 5=excruciating pain. The results showed that 50% (n=20) of patients experienced a decrease in reported pain levels (Table 13). Eleven patients reported increased pain, eight of whom attributed the change to the honey dressing specifically. This was something the earlier review by Fox¹⁵⁸ had not identified as a side effect. Dunford and Hanano (2004) also noted that patients whose wounds were larger at baseline reported that their pain increased or there was a sustained elevation of pain. In turn, when wound size was reduced there was a decrease

in pain. None of the other studies reviewed discussed the link between wound size and reported pain levels, so it is difficult to draw any definitive conclusions about this aspect.

Vandamme et al¹⁶² published a review of *Honey in modern wound care* in the *Burns* journal. Of the 55 studies included, 19 related to chronic wounds (VLU, DFU, PU/PI). Examining evidence published up to July 2012, Vandamme and colleagues discussed one RCT which examined pain as a

primary outcome suggesting that honey has a statistically significant effect on pain. Five studies reported measuring the parameters of wound pain with two reporting a positive effect, but this was not statistically significant (Table 14). Over half of the studies in the review did not report pain as an outcome measure.¹⁶²

A review in the same year by Yaghoobi et al¹⁶³ examined the evidence for the antioxidant, antibacterial and anti-inflammatory properties of honey. The review was included as it is well-known that pain is a sign of inflammation;

Table 13: Summary of pain scores and percentage wound reduction and rate of wound reduction, reproduced from Dunford and Hanano (2004)⁶¹

| Pain group | No. | Pain score at recruitment | Pain score at study end | Wound size at recruitment (cm ²) | Wound size study end (cm ²) | % wound reduction | % wound reduction week (healing rate) |
|--|-----|---------------------------|-------------------------|--|---|-------------------|---------------------------------------|
| No pain | 4 | 0 | 0 | 2.97 ±2.87 ⁷ | 2.42 ±3.03 | 20.46 ±78.84 | 12.02 ±25.92 |
| Pain decreased | 20 | 1.7 ±0.8 ² | 0.15 ±0.37 | 7.86 ±7.62 | 3.98 ±7.73 | 57.42 ±46.67 | 10.31 ±14.98 |
| Pain remained the same | 5 | 3.0 ±1.58 ⁵ | 3.0 ±1.58 ⁶ | 17.35 ±24.82 | 15.07 ±21.23 | 24.76 ±52.45 | 1.82 ±5.61 |
| Pain increased (incl. dropouts) ¹ | 11 | 1.36 ±1.21 ³ | 2.27 ±1.56 | 11.94 ±13.39 | 12.94 ±15.39 | -6.42 ±75.22 | 0.08 ±9.88 |
| Pain dropouts | 6 | 2.17 ±0.98 ⁴ | 3.33 ±1.21 | 20.71 ±20.27 | 23.46 ±21.5 | -19.23 ±86.14 | -2.16 ±27.55 |

- 1 Includes two patients with same pain level between recruitment and study end, but with higher levels in between
- 2 Significant difference in pain score between recruitment and study end ($p=-3.54 \times 10^{-9}$; paired student t-test)
- 3 Significant difference in pain score between recruitment and study end ($p=-2.31 \times 10^{-4}$; paired student t-test)
- 4 Significant difference in pain score between recruitment and study end ($p=-9.17 \times 10^{-4}$; paired student t-test)
- 5 Significant difference in pain score at recruitment between patients whose pain level remained the same and patients whose pain decreased or increased ($p=-0.014$ and -1.87×10^{-4} ; respectively; unpaired student t-test)
- 6 Significant difference in pain score at study end between patients with the same pain and those whose pain decreased ($p=-7.92 \times 10^{-4}$; unpaired student t-test)
- 7 Significant difference in pain score between recruitment and study end ($p=-0.0028$; paired student t-test)

Table 14: Outcomes of the included studies by wound category and design, reproduced from Vandamme et al (2013)¹⁶²

| Outcome | Antibacterial effect | Healing | Debridement | Anti-inflammatory | Odour reduction | Wound pain reduction |
|----------------------------|----------------------|---|-------------|-------------------|-----------------|---|
| <i>Burns: RCTs</i> | | | | | | |
| Baghel et al. (66) | ++ | ++ | + | 0 | 0 | 0 |
| Malik et al. (39) | + | ++ | 0 | / | 0 | 0 |
| Subrahmanyam (40) | ++ | ++ | / | 0 | / | + |
| Subrahmanyam (37) | ++ | ++ | / | 0 | / | / |
| Subrahmanyam (41) | ++ | ++ | 0 | 0 | 0 | ± |
| Subrahmanyam (38) | / | ++ | + | + | 0 | 0 |
| Subrahmanyam (36) | -- | 0 | 0 | 0 | 0 | 0 |
| <i>Ulcers: RCTs</i> | | | | | | |
| Gethin and Cowman (35) | + | 0 | 0 | 0 | 0 | ++ |
| Gethin and Cowman (34) | / | ++ | + | 0 | 0 | 0 |
| Jull et al. (27) | ± | ± | 0 | 0 | 0 | 0 |
| Shukrimi et al. (67) | ± | ± | 0 | + | + | 0 |
| Yaqucu Günes (65) | 0 | ++ | 0 | 0 | 0 | 0 |
| <i>Ulcers: CCT</i> | | | | | | |
| Oluwatosin et al. (62) | 0 | - | 0 | 0 | 0 | ± |
| <i>Others wounds: RCTs</i> | | | | | | |
| Abdulrhman et al. (74) | 0 | ++ | 0 | 0 | 0 | 0 |
| Al-Waili and Saloom (70) | ++ | ++ | 0 | / | 0 | / |
| Chang et al. (77) | 0 | ± | 0 | ± | 0 | 0 |
| English et al. (28) | / | 0 | 0 | ++ | 0 | 0 |
| Ingle et al. (68) | 0 | + (shallow wounds) and - (abrasions) | 0 | 0 | 0 | 0 |
| Khanal et al. (69) | 0 | ++ | 0 | ++ | 0 | 0 |
| Lund-Nielsen et al. (75) | 0 | ± | ± | ± | ± | ± |
| McIntosh and Thomsen (76) | 0 | -- (partial avulsion) and + (total avulsion) | 0 | 0 | 0 | ± |
| Moolenaar et al. (33) | 0 | + | 0 | 0 | 0 | + |
| Mphande et al. (72) | + | + | 0 | 0 | 0 | + |
| Okeniyi et al. (71) | 0 | ++ | ++ | ++ | 0 | 0 |
| Robson et al. (75) | 0 | + | / | 0 | 0 | 0 |
| Robson et al. (73) | ± | / | 0 | 0 | / | 0 |
| <i>Other wounds: CCT</i> | | | | | | |
| Misirioglu et al. (64) | 0 | ++ (paraffin and saline) and ± (hydrocolloid) | 0 | 0 | 0 | ++ (paraffin and saline) + (hydrocolloid) |

++: significantly different and in advantage of honey; +: in advantage of honey but not significantly different; ±: no difference between the therapy regimes; -: in disadvantage of honey but not significantly different; --: significantly different in disadvantage of honey; /: not compared; 0: not reported.

The numbers in left column refer to references in Vandamme et al.¹⁶²

therefore, it was relevant to the subject of wound-related pain. Yaghoobi and colleagues proposed that the anti-inflammatory action of honey leads to a reduction in oedema and exudate production.¹⁶³ Citing Simon et al (2009), Yaghoobi et al discussed that the anti-inflammatory effect of honey also reduces pain caused by pressure on nerve endings and reduces the amount of prostaglandin produced in the inflammatory process (see Chapter 2: The Multidimensional Nature of Pain for more on the role of prostaglandin in inflammation).

Yaghoobi et al¹⁶³ concluded that the evidence for the use of honey was stronger for burn injuries than for individuals with chronic leg ulcers with regard to pain relief. However the review included animal as well as human studies and the authors did not report the number of studies or participants separately to determine the reliability of the review. Oryan et al¹⁶⁴ presented a narrative review of the mechanisms and therapeutic properties of honey on wound healing. Similar to the review by Yaghoobi et al¹⁶³. Oryan and colleagues discussed the anti-inflammatory properties of honey and based on evidence from six studies, proposed that honey can help to reduce oedema and pain. A more recent review by Anastasiou et al¹⁶⁵ examined the *in vitro* and *in vivo* evidence for the therapeutic properties of honey to inform its use for individuals with DFU. The review focused on animal wounds specifically, which limits the external validity to some degree; however, Oryan et al suggested that honey can reduce prostaglandin levels and thus decrease oedema, exudation and inflammation. Oryan et al also proposed that the effect was to reduce 'topical' pain. The implications for peripheral or nociceptive pain are not clear (165).

Yaghoobi and colleagues also proposed that honey can contribute to the painless lifting of sloughy tissue due to its debridement action (163); this view was echoed by Anastasiou et al. (165). Whilst this does not relate to the management of wound-related pain *per se*, it is a clinically important consideration in the wider context of holistic management of pain in relation to wound bed preparation and debridement.

In a recent review of the use of honey in the management of nonhealing wounds, Vyhliđalová et al. (166) examined data from 13 primary studies (RCTs n=8, Prospective studies n=5). The number of participants in the assessed studies ranged from 10 to 375, and all but one was related to adults. Six of the studies investigated the effect of honey on

the management of DFU, two pertaining to individuals with LU and one MFW; the remaining studies included wounds of various aetiologies. Vyhliđalová and colleagues (166) did not comment on the findings related to pain in their conclusion, but examination of the individual studies (Biglari et al. 2013, Gulati 2014, and Mohamed 2015) provided evidence of a decrease in the pain levels during the study (based on a VAS scale). Biglari et al. (2013) also reported on the reduction of the need for analgesics during dressing changes.

The most recent review of honey was undertaken by Yilmaz et al¹⁶⁷ who examined RCTs (n=30) published between 2009–2019. The studies represent findings from a range of geographical locations including Pakistan, Iran, India, Saudi Arabia, Denmark, Indonesia, Greece, China, the Czech Republic and the UK. They concluded that honey provided rapid epithelization and wound contraction in wound healing, had an anti-inflammatory and debridement effect, decreased pain, ensured infection control, shortened wound healing time and was cost-effective. Four of the studies included mentioned pain as a specific outcome, one of which related to burn injuries, and three included patients with chronic wounds. Dubashi and Sindwani (168) compared the use of honey to phenytoin in 150 patients (group A, 50 patients treated with honey; group B, 50 patients treated with phenytoin; group C, 50 patients treated with saline dressings). The underlying wound aetiology was wound infections (n=32), trophic ulcers (n=33), DFUs (n=51), venous ulcers (n=22) and pressure sores (*sic*) (n=12). Pain was assessed using a Visual Analog Scale (VAS) on days 5, 10, 15 and 20. Table 15 shows the pain scores at each time point.¹⁶⁸

Yilmaz et al proposed that the experience of pain is reduced due to the anti-inflammatory activity of honey, but this is speculative rather than based on data from their study.

Zeleníková and Vyhliđalová¹⁶⁹ reported on the results of a prospective interventional study in elderly persons receiving home care (n=40). The intervention group was treated with honey (n=20), and the control group (n=20) had conventional dressings, with the patients being followed up for three months. The Wound Healing Continuum (WHC) guided the assessment, and a VAS was used to assess pain intensity. Wound aetiologies included PUs (n=7), lower leg ulcers (n=9) and diabetic foot syndrome (n=4). Zelenikova and Vyhliđalova reported that there was a statistically

significant difference in pain intensity between the two groups ($p=0.0007$), with higher pain scores being indicated by controls (169). Table 16 shows the differences in pain intensity reported between the two groups at dressing change on Day 1 and Day 20. While the results for Day 20 are statistically significant ($p 0.0007$), Zelenikova and Vyhídalova do not report on the pain intensity scores in the intervening 19 days to determine any variance in reported pain. This limits the conclusions that can be drawn.

Rojczyk et al¹⁷⁰ undertook a review of Polish research on propolis and its medical application for wound healing. While pain was mentioned as an outcome, this was in relation to a symptom of mouth ulcers. Rojczyk and colleagues discuss the anti-inflammatory properties of honey but in relation to the physiological response in wound healing rather than as a potential approach to the treatment of wound-related pain.

Overall, the evidence of the use of honey for the management of wound-related pain seems to indicate that the effects may be related to its anti-inflammatory properties.

7.5 Effects of aromatherapy and music on pain

Liberato et al¹⁴⁶ reviewed the evidence for a range of nursing interventions for the management of pain in patients with VLU. They undertook their search in June 2015 and identified seven studies for inclusion. Liberato and colleagues reported on a pilot study by Kane et al¹⁵⁵ which examined the use of 'odour therapies' (lavender and lemon) and music therapies (relaxing and preferred music). The sample size was small ($n=8$), mainly male ($n=5$), with a mean age of 70.1 years. The SF-MPQ was used, which comprises a 10cm line (no pain to worst possible pain), and the Present Pain Inventory (PPI) was also used. It is a 6-point verbal descriptor scale, rated 0–6. Kane et al¹⁵⁵ observed that pain increased during the dressing change procedure, and the lavender odour therapy reduced pain immediately after the procedure. For the music therapies, the study demonstrated no significant effects on pain intensity either during or after the dressing change. Kane et al suggested that the relaxing music, and not the preferred music, may have an analgesic effect (reduced pain intensity) after

Table 15: Comparison of pain score at the 5th, 10th, 15th and 20th days, reproduced from Dubashi and Sindwani (2015)¹⁶⁸

| Parameter | Numbers of patients | Pain score | | | | | | | |
|-----------|---------------------|------------|------|----------|------|----------|------|----------|------|
| | | 5th day | | 10th day | | 15th day | | 20th day | |
| | | Mean | SD | Mean | SD | Mean | SD | Mean | SD |
| Group A | 50 | 5.10 | 0.79 | 3.06 | 0.91 | 2.06 | 0.65 | 1.20 | 0.45 |
| Group B | 50 | 5.54 | 0.68 | 3.76 | 0.77 | 2.68 | 0.65 | 1.90 | 0.51 |
| Group C | 50 | 6.72 | 0.64 | 5.02 | 0.77 | 4.32 | 0.79 | 3.14 | 0.76 |
| F value | | 70.65 | | 73.30 | | 138.09 | | 140.42 | |
| P value | | <0.0001 | | <0.0001 | | <0.0001 | | <0.0001 | |
| A vs B | | <0.01 | | <0.0001 | | <0.0001 | | <0.0001 | |
| A vs C | | <0.0001 | | <0.0001 | | <0.0001 | | <0.0001 | |
| B vs C | | <0.0001 | | <0.0001 | | <0.0001 | | <0.0001 | |

Table 16: Differences in pain intensity between groups, adapted from Zeleniková and Vyhídalová (2019)¹⁶⁹

| Time | Group | Pain intensity - VAS | | | | | | p-value ^a |
|--------|--------------|----------------------|--------|-------------|------|------|------|----------------------|
| | | Number | Median | Arith. mean | SD | Min. | Max. | |
| Day 1 | Intervention | 20 | 3 | 3.3 | 1.53 | 1 | 8 | 0.1516 |
| | Control | 20 | 4 | 3.9 | 1.59 | 1 | 6 | |
| Day 20 | Intervention | 20 | 2 | 1.7 | 1.53 | 0 | 5 | 0.0007 |
| | Control | 20 | 3.5 | 3.8 | 1.70 | 1 | 6 | |

^a Mann-Whitney U test.

the dressing change; however, no statistically significant difference was shown. These results are based on one small pilot study, so making specific recommendations for either therapy is difficult.

7.6 Evidence to support therapies for malignant fungating wounds (MFWs) and pain

Tsichlakidou et al¹⁷¹ examined interventions to support symptom management (malodour, exudate, pain and bleeding) in individuals with MFWs. The treatments investigated included manuka honey, NPWT and foams (with and without silver). The review was limited to evidence indexed on Medline only. Tsichlakidou et al identified a range of evidence (n=9), including cross-sectional studies, 'patient group study', qualitative/descriptive/cross-sectional, RCTs and case studies. The review cites evidence published up to 2017. Tsichlakidou and colleagues conclusion centred around the use of oral opioids to manage pain, but a number of individual studies discussed the use of different dressings to manage wound-related pain¹⁷¹. This included Maund (2008), who reported on the use of an ionic sheet hydrogel dressing for pain relief. Lund-Nielsen (2011) compared the use of honey-coated bandages compared with silver-coated bandages and found no statistically significant difference in terms of wound size, cleanliness, malodour, exudation and wound pain. (Note: please also see the discussion of topical analgesics and anaesthetics in Chapter 4, Section 4.6).

7.6.1 Traditional Chinese medicine (TCM)

Two systematic reviews examined the use of TCM, specifically the genus *Desmodium* species, in terms of its anti-inflammatory, anti-pyretic and analgesic activity. Ma et al¹⁷² included experimental, animal and human studies; however, it's not clear how many studies and participants were included. The article was a narrative synthesis of the available evidence with inhibition of pain discussed in relation to joint, rheumatoid, stomach, ear, lumbar and traumatic swelling. There was no discussion of the use of *Desmodium* species for wound-related pain.

Li et al¹⁷³ evaluated the effectiveness of the external application of TCM (EA-TCM) in individuals with VLU. Li and colleagues included 16 studies with a total of 1269 participants. Across the studies, there were 660 subjects in the experimental groups and 609 in the controls. The sample sizes ranged from 51–164. The TCM interventions included

ointments (n=9 studies), powders (n=3 studies), Chinese-herb external washing (n=3 studies), paste and oil (n=1 in each case). Comparison of the same interventions showed that there were significant differences in total effectiveness rates between EA-TCM and conventional therapy groups (RR=1.22, 95% confidence interval [CI]=1.16– 1.29, and $P<0.00001$). Compared to conventional therapy, EA-TCM combined with conventional therapy had a superior total effectiveness rate (RR=1.11, 95% CI=1.04–1.19, and $P=0.003$). There were no significant differences in recurrence rates during follow-up and final pain measurements between the experimental and those in the control groups (RR=0.86, 95% CI=0.31–2.39, and $P=0.85$; MD -0.75, 95% CI= -2.15–0.65, and $P=0.29$). Two of the studies reported final pain measurements: Xu (2012) and Zhang (2013). The pooled results showed that there was a difference between the intervention and control groups.

Li et al stated that due to the low methodological quality of the studies, it was difficult to draw conclusions. Based on these reviews, there appears to be a lack of strong evidence for the use of TCM for the management of wound-related pain.

7.7 Anthocleista

Anyanwu et al¹⁷⁴ reviewed ethnobotany, phytochemistry and pharmacology of the genus *Anthocleista*, of which there are approximately 50 species. This plant is used as a form of traditional medicine in Africa. Anyanwu et al sought to determine its effects on various conditions, including pain. Where pain was mentioned, this related to chest and abdominal pain treatment. In relation to pain associated with wounds and inflammation, the nature of the injury was unclear; therefore, it was difficult to draw any conclusions about its effects on wound-related pain.

7.8 Non-specific reviews

Ongarora¹⁷⁵ explored the topic of technological improvements in the management of chronic wounds, specifically to identify advances in alleviating pain, promoting healing or controlling wound infections. The author included 'articles in scientific journals' (n=119) which had been published after the year 2000. With regard to the management of pain, Ongarora discussed one study which used low-dose topical steroids (LDTs) in patients with chronic wounds (n=34) across three centres over a three month period (176). Pain levels were assessed using a patient-rated VAS (0–10) as 'no response', 'poor response'

(<50% reduction), 'good response' (>50% reduction) and 'total' (no pain, VAS rating 0). Table 17 summarises the outcomes for the LDTS.

The overall conclusion was that it accelerated healing, reduced pain, and controlled the formation of hypergranulation tissue formation in 79% (n=27) patients. Ongarora proposed that LDTS suppressed inflammation, which positively influenced healing and pain relief. However, they cautioned that careful monitoring is required because of the risk of sensitisation. No other studies were found that examined the use of topical LDTS.

7.9 Low-level laser technology (LLLT)

Peplow et al¹⁷⁷ reported on the evidence base for the use of low-level laser technology (LLLT) for pain relief and wound healing. This systematic review examined research from animal (n=16 studies) and human studies (n=15). The human studies provided a total of 41 patients from case studies and observational studies. While patients had mainly acute wounds the review was included as it discussed the use of the therapy as laser acupuncture therefore it was deemed relevant in the wider context of wound-related pain. Five studies examined the effect of LLLT on pain and inflammation where the pain was measured using a modified VAS (self-evaluation) or by more subjective measures ('patients reporting of pain'). While many studies focused on outcomes associated with the effect of LLLT to stimulate wound healing, the studies also reported positive outcomes regarding the therapy's ability to decrease pain and inflammation. As none of the studies examined the

effect of LLLT on wound-related pain specifically, it is difficult to draw firm conclusions. However, the evidence points to a potential gap in the research regarding the use of this technology to treat wound-related pain.

7.10 Summary of recommendations

Based on a thorough review of available resources and clinical experience, it is very difficult to recommend practices of complementary and alternative medicine that have a clear positive impact on wound-related pain. The available studies that have used various alternative approaches have not always assessed pain as a primary outcome and have used different rating scales to measure pain intensity. In terms of the evidence base for complementary and alternative medicine, one aspect that could strengthen future research is to move away from using solely unidimensional tools to assess pain, such as VAS and NRS and instead use multidimensional scales and tools that facilitate the assessment of the nature of the pain and other parameters. More specifically, most of the studies did not examine wound-related pain specifically, however this is partly understandable as it is difficult to isolate the experience of pain because of its multidimensional nature.

It was not possible to present a GRADE EtD framework, which is a systematic and transparent approach to making well informed healthcare choices, due to the lack of systematic and well-designed studies addressing the influence of complementary and alternative medicine on wound-related pain. Therefore, for this chapter it was not possible to prepare a summary of recommendations for

Table 17: Outcomes achieved with topical corticosteroid treatment (adapted from Ongarora 2022) (175)

| Indication outcome (n=34) | No response | Poor response | Good response (pain) | Good response (wound area) ⁺ | Full pain relief or complete healing |
|-------------------------------------|-------------|---------------|----------------------|---|--------------------------------------|
| Reduced pain (n=27) | | 1 | 2 | 22 | 2 |
| Simulated healing (n=28) | 2 | 2 | N/A | 18 | 6 |
| Reduction of hypergranulation (n=2) | 0 | 0 | N/A | 2 | 0 |
| Reduced exudate (N=7) | 0 | 1 | 6 | N/A | 0 |

*There were often more than one indication for treatment

⁺ >50% reduction.

clinical practice. Therefore is a need for new studies that directly investigate the impact of complementary and alternative approaches on pain in individuals with wounds.

7.11 Key points

- There is some evidence to support the role of honey for the management of wound-related pain, specifically the research indicates that the analgesic action may be related to its anti-inflammatory properties. This helped to reduce localised oedema and exudate which in turn reduces the effects of prostaglandin and therefore the pressure on nerve endings. Some studies also reported a reduction in pain intensity. Much of the evidence for honey relates to leg ulcers and one study reported an increase in pain with the use of honey, therefore the evidence is contradictory in some respects. Also, in relation to honey, due its debridement properties, the evidence suggests that the effect on pain is in relation to quicker wound closure.
- There is limited evidence to support the use of aromatherapy and music, however these approaches may help in terms of providing a ‘distraction’ and, as they are unlikely to be harmful, it’s certainly worth discussing with individuals whether they would find these helpful.
- Evidence for TCM, Plants, LDTs and LLLT was very weak.

8. Challenges and next steps for the holistic management of wound-related pain

The experience of pain is subjective and complex; therefore, approaches need to consider and include the psychological aspects as well as the social factors that affect the individual. Hence a multidisciplinary approach, with different healthcare professionals and expertise, is needed. Yet despite advances in pain assessment and pain management over the last three decades, pain is not always managed effectively.^{178, 179} It has been argued that there has been a lack of referrals to pain services or cross-team working, such as between those in wound care and pain management, in caring for individuals with chronic wounds and persistent pain.¹⁸⁰ This situation may be related to individual and healthcare-related barriers to pain and wound management.

System-related factors include the lack of clearly defined standards and pain management protocols, and limited access to pain specialists and, in some instances, appropriate analgesics due to healthcare policies and economy.^{181,182} In the healthcare profession, barriers to effectively managing pain may include personal attitudes, beliefs, culture, sensitivity, and knowledge and understanding.¹⁸³ In individuals with pain, barriers may relate to genetics, culture, spirituality, prior experience, anxiety, attitudes and beliefs about pain and how pain management affects the experience of pain, knowledge, and understanding.^{184,185,186,187}

Several authors have identified a gap in the education of undergraduate healthcare students throughout the western world with regards to the topic of pain education.^{188,189,190,191} Furthermore, clinicians report not feeling confident about managing those with chronic pain.¹⁹² As a consequence, this can influence attitudes about pain and health outcomes of individuals with pain.^{193,194,191} A systematic review by Ortiz et al,¹⁹⁵ found that nurses' knowledge of pain was positively related to previous pain training, highlighting the need to ensure appropriate pain education provision in preparing students for clinical practice.

There is a paucity of evidence examining patients' knowledge and understanding of wound-related pain specifically and

how clinicians communicate it. This is a significant gap in the literature, given the multidimensional nature of pain and the influence of biopsychosocial factors. This could be addressed by future research exploring individuals' knowledge and understanding of wound-related pain. Until new evidence emerges to inform patient education for wound-related pain, there are opportunities to develop patient information brochures and booklets to support knowledge and understanding. Additionally, digital forms of information can be provided via social media, videos, and software applications to encourage improved pain literacy. Importantly, patient information should be provided in a structured way which facilitates active engagement and shared-decision making as a part of patient-centred care. Sometimes people worry about overusing analgesics and, conversely, others overuse them. Therefore, it is essential to increase health literacy and financial literacy to improve pain management and keep patients in partnership in the care process. This can include increasing understanding that improper use of pain medication can lead to further complications.¹⁹⁶

Overall, there is a lack of prospective studies focusing on the management of wound-related pain and effective treatment strategies.

Gaps in the evidence base

It is acknowledged that different approaches are used in the chronic pain settings, as part of the multidisciplinary approach to pain management. For example, Pain Neuroscience Education (PNE) is used as part of physiotherapy/manipulative approaches,¹⁹⁷ however, there was no evidence found in this literature search for education in those with chronic wound-related pain. The evidence base for pharmacological therapeutics that may be of benefit for individuals with wound-related pain also warrants consideration. These areas could be considered in the future for further research.

In this document, we discussed the potential role of distraction therapy to help with the management of procedural pain. Evidence from the study of individuals with

complex regional pain syndrome suggests that rather than distraction strategies, approaches that foster attentional orienting to a painful sensation is more effective. It's not known if this is also the case for individuals with wound-related pain, but it is certainly worth exploring to determine the best strategy.

We are aware that there are a number of studies examining interventions such as electrical stimulation and the role that may have in managing pain; however, our search did not identify an existing systematic review that has examined the evidence base. Such a review is needed to inform clinical practice.

One-page summary: holistic management of wound-related pain

Holistic Management of Wound-Related Pain



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The experience of wound-related pain is complex and needs to take into consideration the psychological and social factors that can impact on an individual's quality of life to ensure a holistic approach.

Pain is a multidimensional phenomenon that is predisposed by biological, psychological and social factors which influence how pain is experienced and how it should be managed (Love-Jones 2019, Faculty of Pain Medicine 2021). Additionally, individuals learn the concept of pain through life experiences (Linton & Shaw 2011, Craig & MacKenzie 2021). Pain, particularly chronic / persistent pain can also have adverse effects on function and on social and psychological well-being (overall quality of life), therefore understanding pain and its management is essential to providing effective pain management.



Assessment of wound-related pain is complex and multidimensional. Health care providers must determine what the most suitable assessment tool is for their patients and in doing so consider an individual's ability to assess their own pain. Unidimensional measures of pain intensity are not appropriate as stand-alone tools for pain assessment. Information from these scales must be considered in conjunction with a functional and sociopsychological assessment. The assessment of chronic pain requires the use of multidimensional tools that incorporate quality of life measures.



Management of wound-related pain needs to consider the impact of:

- Anticipatory pain
- Procedural pain (i.e. related to the nursing interventions and care – debridement procedures)

Interventions (as adjuncts to pharmacological approaches) might include:

- Physical activity / exercise – active and Physical activity – passive and repositioning
- Manage moisture to prevent maceration and reduce risk of pain from periwound skin irritation (dermatitis)
- A combination of non-pharmacological interventions may be needed
- Aromatherapy and music therapy may also be helpful in providing a distraction for anticipatory and procedural related pain
- Topical impregnated dressings and topical anaesthetics for pain relief
- Honey impregnated dressings appear to have an analgesic action related to its anti-inflammatory properties
- For individuals with leg ulcers social models of care and motivation enhancement programmes may be helpful.



Patient Education approaches for wound-related pain should include information on:

- Aetiology of the wound and causes of pain (based on OPQRST framework),
- Non-pharmacological and pharmacological methods for pain relief
- Ways and means of judging the effectiveness of interventions to manage wound-related pain
- Impact of pain on quality of life
- Patient education maybe include: the rationale and goals of treatment (particularly expectation setting)



Psychological approaches need to consider the factors associated with pain i.e., attention, cognitions, emotions, emotion regulation and overt behaviour. Interventions may include:

**Distraction · Interceptive Exposure · Cognitive Restructuring · Cognitive Behavioural Therapies
Activation · Relaxation · Positive Psychology Techniques · Coping Strategies**

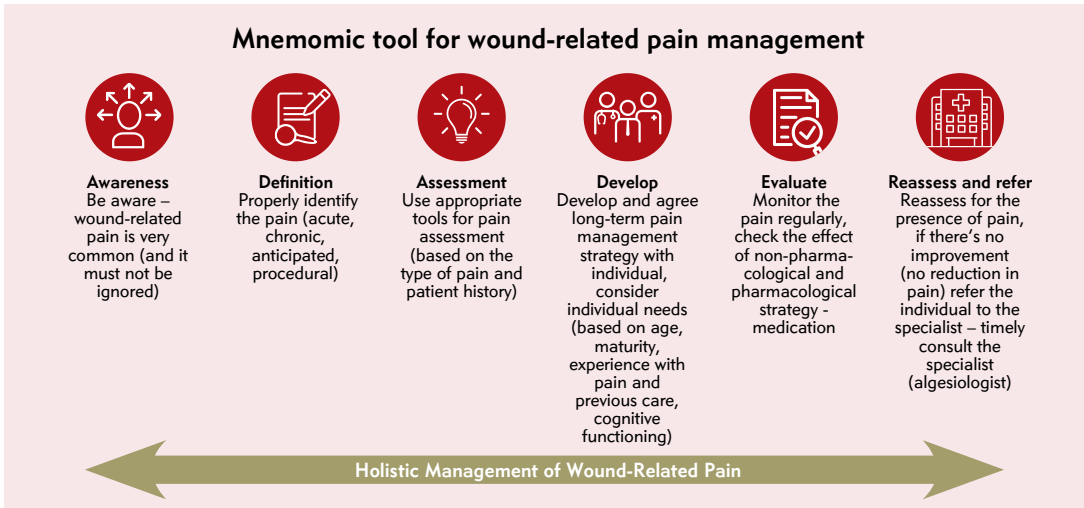
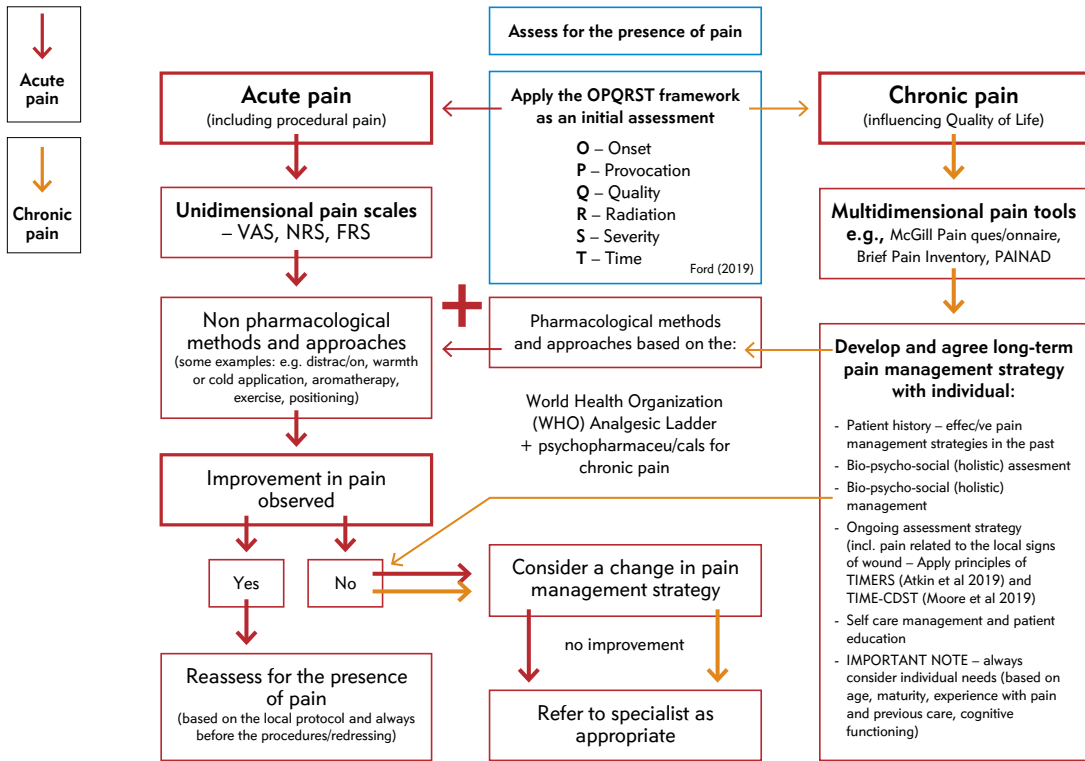
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Decision-aid to support the holistic management of wound-related pain



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9. Resources to support knowledge and education for the holistic management of wound-related pain

EWMA wound curricula (physicians and nurses)

- Wound Healing Curriculum (2015). (Adopted in 2018 by UEMS and approved as the official ETR for specialisation in wound healing for physicians)
- Wound Curriculum for Student Nurses – EQF level 4 (2021)
- Wound Curriculum for Nurses – EQF levels 5 – 7 (2017, 2019, 2020)

EWMA E-Learning

- Module 6: Introduction to Pain in Wound Management (2022)

EWMA projects and documents

- EWMA Document: The Impact of Patient Health and Lifestyle Factors on Wound Healing (2022)
- EWMA Document: Evidence for Person-Centred Care in Chronic Wound Care (2020)
- EWMA Video project: Living with Chronic Wounds (2018)

Resources are available for free reading and download at www.ewma.org

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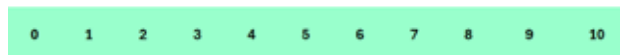
11. Appendices

Appendix 1: Pain Assessment Tools

Numerous representations

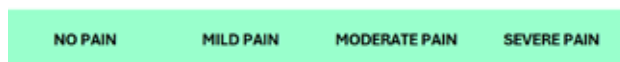
There are numerous representations of the NRS, VRS and VAS rating scale are available in the public domain. Below are examples of these.⁷⁶

Numerical rating scale



Ask the patient on a scale of 0-10, where 0=no pain and 10=worst pain, to choose a number that best places his/her current level of pain

Verbal rating scale



Ask the patient which word best describes his/her current level of pain

Visual analogue scale



Ask the patient to pick up a point on the continuum that best reflects how she/he is feeling

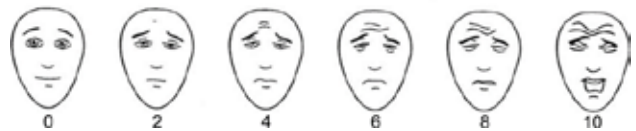
Faces Pain Scales

Wong-Baker FACES Scale¹⁹⁸



Ask the patient to choose a face that best describes how he/she is feeling

Faces Pain Scale – Revised¹⁰³



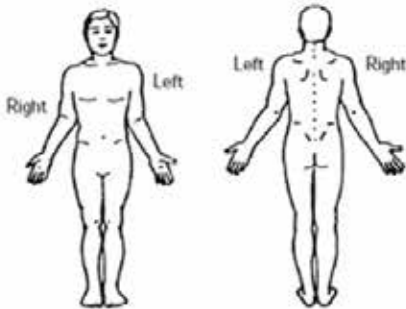
Brief Pain Inventory¹⁹⁹

Date: ___/___/___ Time: _____
Name: _____
Last First Middle initial

1) Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?

1. Yes 2. No

2) On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.



3) Please rate your pain by circling the one number that best describes your pain at its **worst** in the past 24 hours.

0 1 2 3 4 5 6 7 8 9 10
No Pain as bad as
pain you can imagine

4) Please rate your pain by circling the one number that best describes your pain at its **least** in the past 24 hours.

0 1 2 3 4 5 6 7 8 9 10
No Pain as bad as
pain you can imagine

5) Please rate your pain by circling the one number that best describes your pain on **average**.

0 1 2 3 4 5 6 7 8 9 10
No Pain as bad as
pain you can imagine

6) Please rate your pain by circling the one number that tells how much pain you have **right now**.

0 1 2 3 4 5 6 7 8 9 10
No Pain as bad as
pain you can imagine

7) What treatments or medications are you receiving for your pain?

8) In the past 24 hours, how much **relief** have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.

0% 10 20 30 40 50 60 70 80 90 100%
No Complete
relief relief

9) Circle the one number that describes how, during the past 24 hours, pain has **interfered** with your:

A. General activity

0 1 2 3 4 5 6 7 8 9 10
Does not Completely
interfere interferes

B. Mood

0 1 2 3 4 5 6 7 8 9 10
Does not Completely
interfere interferes

C. Walking ability

0 1 2 3 4 5 6 7 8 9 10
Does not Completely
interfere interferes

D. Normal work (includes both work outside the home and housework)

0 1 2 3 4 5 6 7 8 9 10
Does not Completely
interfere interferes

E. Relations with other people

0 1 2 3 4 5 6 7 8 9 10
Does not Completely
interfere interferes

F. Sleep

0 1 2 3 4 5 6 7 8 9 10
Does not Completely
interfere interferes

G. Enjoyment of life

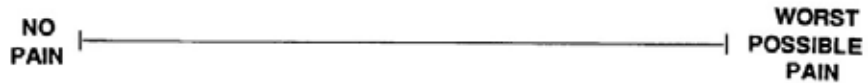
0 1 2 3 4 5 6 7 8 9 10
Does not Completely
interfere interferes

SHORT-FORM MCGILL PAIN QUESTIONNAIRE

PATIENT'S NAME: _____

DATE: _____

| | NONE | MILD | MODERATE | SEVERE |
|-------------------|-------------|-------------|-----------------|---------------|
| THROBBING | 0) _____ | 1) _____ | 2) _____ | 3) _____ |
| SHOOTING | 0) _____ | 1) _____ | 2) _____ | 3) _____ |
| STABBING | 0) _____ | 1) _____ | 2) _____ | 3) _____ |
| SHARP | 0) _____ | 1) _____ | 2) _____ | 3) _____ |
| CRAMPING | 0) _____ | 1) _____ | 2) _____ | 3) _____ |
| GNAWING | 0) _____ | 1) _____ | 2) _____ | 3) _____ |
| HOT-BURNING | 0) _____ | 1) _____ | 2) _____ | 3) _____ |
| ACHING | 0) _____ | 1) _____ | 2) _____ | 3) _____ |
| HEAVY | 0) _____ | 1) _____ | 2) _____ | 3) _____ |
| TENDER | 0) _____ | 1) _____ | 2) _____ | 3) _____ |
| SPLITTING | 0) _____ | 1) _____ | 2) _____ | 3) _____ |
| TIRING-EXHAUSTING | 0) _____ | 1) _____ | 2) _____ | 3) _____ |
| SICKENING | 0) _____ | 1) _____ | 2) _____ | 3) _____ |
| FEARFUL | 0) _____ | 1) _____ | 2) _____ | 3) _____ |
| PUNISHING-CRUEL | 0) _____ | 1) _____ | 2) _____ | 3) _____ |



P P I

- 0 NO PAIN _____
- 1 MILD _____
- 2 DISCOMFORTING _____
- 3 DISTRESSING _____
- 4 HORRIBLE _____
- 5 EXCRUCIATING _____

© R. Melzack, 1984.

The short-form McGill Pain Questionnaire (SF-MPQ). Descriptors 1-11 represent the sensory dimension of pain experience and 12-15 represent the affective dimension. Each descriptor is ranked on an intensity scale of 0 = none, 1 = mild, 2 = moderate, 3 = severe. The Present Pain Intensity (PPI) of the standard long-form McGill Pain Questionnaire (LF-MPQ) and the visual analogue scale (VAS) are also included to provide overall intensity scores.

Coping Strategies Questionnaire²⁰¹

ONE- AND TWO-ITEM VERSIONS OF THE COPING STRATEGIES QUESTIONNAIRE (CSQ)

Instructions: Individuals who experience pain have developed a number of ways to cope, or deal with, their pain. These include saying things to themselves when they experience pain, or engaging in different activities. Below is a list of things that people have reported doing when they feel pain. For each activity, please indicate, using the scale below, how much you engage in that activity when you feel pain, where a 0 indicates you never do that when you are experiencing pain, a 3 indicates you sometimes do that when you are experiencing pain, and a 6 indicates you always do it when you are experiencing pain. Remember, you can use any point along the scale.

| | | | | | | |
|----------|---|---|----------------------|---|---|----------------|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| Never do | | | Sometimes do that | | | Always do that |

When I feel pain...

Single-item CSQ:

- 1. I think of things I enjoy doing.....0 1 2 3 4 5 6
- 2. I just think of it as some other sensation, such as numbness0 1 2 3 4 5 6
- 3. It is terrible and I feel it is never going to get any better0 1 2 3 4 5 6
- 4. I don't pay any attention to it0 1 2 3 4 5 6
- 5. I pray for the pain to stop0 1 2 3 4 5 6
- 6. I tell myself I can't let the pain stand in the way of what I have to do0 1 2 3 4 5 6
- 7. I do something active, like household chores or projects0 1 2 3 4 5 6

Two-item CSQ scales consist of the above plus the following:

- 8. I replay in my mind pleasant experiences in the past0 1 2 3 4 5 6
- 9. I pretend it is not a part of me0 1 2 3 4 5 6
- 10. I feel I can't stand it anymore0 1 2 3 4 5 6
- 11. I ignore it0 1 2 3 4 5 6
- 12. I try to think years ahead, what everything will be like after I've gotten rid of the pain0 1 2 3 4 5 6
- 13. I see it as a challenge and don't let it bother me0 1 2 3 4 5 6
- 14. I do something I enjoy, such as watching TV or listening to music0 1 2 3 4 5 6

Scoring instructions: Items 1, 2, 3, 4, 5, 6, and 7 represent the CSQ Diverting Attention, Reinterpreting Pain Sensations, Catastrophizing, Ignoring Sensations, Praying or Hoping, Coping Self-Statements, and Increased Behavioral Activities scales, respectively. The respondent's rating for each of these items is the score for that scale. Items 8, 9, 10, 11, 12, 13, and 14 are the second items in each of the CSQ scales, respectively. Scores for the two-item CSQ scales are the averages of the two items on each scale.

Abbey Pain Scale

For measurement of pain in people with dementia who cannot verbalise

How to use scale: While observing the resident, score questions 1 to 6

Name of resident: _____

Name and designation of person completing the scale: _____

Date: _____ Time: _____

Latest pain relief given was: _____ at _____ hours

Q1. Vocalisation

eg. whimpering, groaning, crying

Absent - 0 Mild - 1 Moderate - 2 Severe - 3

Q1

Q2. Facial Expression

eg. looking tense, frowning, grimacing, looking frightened

Absent - 0 Mild - 1 Moderate - 2 Severe - 3

Q2

Q3. Change in Body Language

eg. fidgeting, rocking, guarding part of body, withdrawn

Absent - 0 Mild - 1 Moderate - 2 Severe - 3

Q3

Q4. Behavioural Change

eg. increased confusion, refusing to eat, alteration in usual patterns

Absent - 0 Mild - 1 Moderate - 2 Severe - 3

Q4

Q5. Physiological Change

eg. temperature, pulse or blood pressure outside normal limits, perspiring, flushing or pallor

Absent - 0 Mild - 1 Moderate - 2 Severe - 3

Q5

Q6. Physical Changes

eg. skin tears, pressure areas, arthritis, contractures, previous injuries

Absent - 0 Mild - 1 Moderate - 2 Severe - 3

Q6

• **Add scores for 1 - 6 and record here:** Total pain score

• **Now tick the box that matches the Total**

0-2 - No Pain 3-7 - Mild 8-13 - Moderate 14+ - Severe

• **Finally tick the box which matches the type of pain**

Chronic Acute Acute on Chronic

The Pain Assessment in Advanced Dementia (PAINAD) scale⁵⁸

| Items | 0 | 1 | 2 | SCORE |
|--|-------------------------|--|---|-------|
| Breathing (Independent of vocalization) | Normal | Occasional labored breathing. Short period of hyperventilation. | Noisy labored breathing. Long period of hyperventilation. Cheyne-stokes respirations. | |
| Negative vocalization | None | Occasional moan or groan. Low level of speech with a negative or disapproving quality. | Repeated troubled calling out. Loud moaning or groaning. Crying. | |
| Facial expression | Smiling or inexpressive | Sad, frightened, frown. | Facial grimacing. | |
| Body language | Relaxed | Tense. Distressed pacing. Fidgeting. | Rigid. Fists clenched. Knees pulled up. Pulling or pushing away. Striking out. | |
| Consolability | No need to console | Distracted or reassured by voice or touch. | Unable to console, distract or reassure. | |
| TOTAL | | | | |

Douleur Neuropathique 4. Screening tool for neuropathic pain²⁰²

DN4[®] QUESTIONNAIRE

Please complete this questionnaire by ticking one answer for each item in the 4 questions below.

Patient Name:

Date:

yes = 1
point

no = 0
points

INTERVIEW OF THE PATIENT

yes

no

QUESTION 1

Does the pain have one or more of the following characteristics?

1. Burning

2. Painful cold

3. Electric shocks

QUESTION 2

Is the pain associated with one or more of the following symptoms in the same area?

4. Tingling

5. Pins and needles

6. Numbness

7. Itching

EXAMINATION OF THE PATIENT

QUESTION 3

Is the pain located in an area where the physical examination may reveal one or more of the following characteristics?

8. Hypoesthesia to touch

9. Hypoesthesia to pinprick

QUESTION 4

In the painful area, can the pain be caused or increased by:

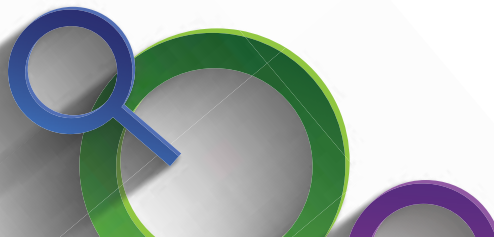
10. Brushing

If the patients score is greater than or equal to 4, the test indicates that your patient is likely to be suffering from neuropathic pain (sensitivity: 83%; specificity: 90%), and further assessment is recommended.¹

Patient's Score: / 10

1. Bouhassira D et al Pain. 2005; 114(1-2):29-36.
DN4[®] 2005 Bouhassira D All rights reserved.

Limited to clinical use by healthcare professional only.



The LANSS Pain Scale^{82,83}

THE LANSS PAIN SCALE
Leeds Assessment of Neuropathic Symptoms and Signs

NAME _____ DATE _____

This pain scale can help to determine whether the nerves that are carrying your pain signals are working normally or not. It is important to find this out in case different treatments are needed to control your pain.

A. PAIN QUESTIONNAIRE

- Think about how your pain has felt over the last week.
- Please say whether any of the descriptions match your pain exactly.

1) Does your pain feel like strange, unpleasant sensations in your skin? Words like pricking, tingling, pins and needles might describe these sensations.

a) NO - My pain doesn't really feel like this (0)

b) YES - I get these sensations quite a lot (5)

2) Does your pain make the skin in the painful area look different from normal? Words like mottled or looking more red or pink might describe the appearance.

a) NO - My pain doesn't affect the colour of my skin (0)

b) YES - I've noticed that the pain does make my skin look different from normal (5)

3) Does your pain make the affected skin abnormally sensitive to touch? Getting unpleasant sensations when lightly stroking the skin, or getting pain when wearing tight clothes might describe the abnormal sensitivity.

a) NO - My pain doesn't make my skin abnormally sensitive in that area (0)

b) YES - My skin seems abnormally sensitive to touch in that area (3)

4) Does your pain come on suddenly and in bursts for no apparent reason when you're still. Words like electric shocks, jumping, and bursting describe these sensations.

a) NO - My pain doesn't really feel like this (0)

b) YES - I get these sensations quite a lot (2)

5) Does your pain feel as if the skin temperature in the painful area has changed abnormally? Words like hot and burning describe these sensations

a) NO - I don't really get these sensations (0)

b) YES - I get these sensations quite a lot (1)

B. SENSORY TESTING

Skin sensitivity can be examined by comparing the painful area with a contralateral or adjacent non-painful area for the presence of allodynia and an altered pin-prick threshold (PPT).

1) ALLODYNIA (Pain caused by something that normally would not cause pain)

Examine the response to lightly stroking cotton wool across the non-painful area and then the painful area. If normal sensations are experienced in the non-painful site, but pain or unpleasant sensations (e.g., tingling, nausea) are experienced in the painful area when stroking, allodynia is present.

a) NO, normal sensation in both areas (0)

b) YES, allodynia in painful area only (5)

2) ALTERED PIN-PRICK THRESHOLD

Determine the pin-prick threshold by comparing the response to a 23 gauge (blue) needle mounted inside a 2 ml syringe barrel placed gently on to the skin in a non-painful and then painful areas.

If a sharp pin prick is felt in the non-painful area, but a different sensation is experienced in the painful area (e.g., none/blunt only [raised PPT] or a very painful sensation [lowered PPT]), an altered PPT is present.

If a pinprick is not felt in either area, mount the syringe onto the needle to increase the weight and repeat.

a) NO, equal sensation in both areas (0)

b) YES, altered PPT in painful area (3)

SCORING:

Add values in parentheses for sensory description and examination findings to obtain overall score.

TOTAL SCORE (maximum 24)

If score <12, neuropathic mechanisms are **unlikely** to be contribution to the patient's pain.

If score ≥12, neuropathic mechanisms are **likely** to be contribution to the patient's pain.

Appendix 2: Summary Table of Evidence for Pain Assessment (Rayyan Project)

| Authors, Year | Aim / Purpose of Systematic Review/ Outcomes | Interventions / phenomena of interest | Databases sourced and searched | Types of Studies Included | Participant details | No. of studies included | Date range of database searching | Pain assessment tools used | Summary of results / findings | Context / Setting / Geographical location of studies included |
|--|--|--|--------------------------------|--|--|-------------------------|----------------------------------|--|--|---|
| De Laat E, Scholte op Reimer W, Van Achterberg T ³³ | Literature search on pressure ulcers and the treatment of pain, malodour and exudate | The diagnosis of pain, malodour and exudate in patients with pressure ulcers | Medline, CINAHL, and Cochrane | Descriptive studies, cross-sectional, randomised double-blind, placebo controlled crossover trial for PU pain. RCTs for PU exudate | Pressure Ulcers | 13 | 1991-2004 | VAS; Faces Rating Scale (FRS); McGill Pain Questionnaire (MPQ) | The MPQ, the VAS and FRS are useful instruments to assess pressure ulcer related pain. Wound malodour is subjectively assessed. Pressure Sore Status Tool is a valid and reliable instrument for assessing the wound healing process | Not indicated |
| Herber O, Schnepf W, Rieger M ³⁴ | To describe or measure the impact of leg ulceration on patients' QoL | Assessment of Quality of life | MEDLINE via PubMed, and CINAHL | 11x quantitative studies 11x qualitative studies and 2x mixed methods studies | Patients with venous leg ulcers or mixed aetiology | 24 | 1990 -2006 | Short-Form Health Survey (SF-36), Nottingham Health Profile (NHP); Life Satisfaction Index; Hospital Anxiety & Depression Scale; Health Locus of Control Scale; NPPS; SF-MPQ | Pain was considered the worst individual item that affects QoL. Leg ulcer patients suffered pain more often than controls. Aetiology of the wounds had an effect on pain experience. Patients with arterial ulcers had more often severe pain than patients with VLU's whereas males experienced more pain than females. In terms of QoL wound related pain influenced physical activities and caused sleeping problems. | UK, Germany, New Zealand, USA, Brazil |

| Authors, Year | Aim / Purpose of Systematic Review/ Outcomes | Interventions / phenomena of interest | Databases sourced and searched | Types of Studies Included | Participant details | No. of studies included | Date range of database searching | Pain assessment tools used | Summary of results / findings | Context / Setting / Geographical location of studies included |
|--|---|--|---|--|--|-------------------------|----------------------------------|--|---|---|
| Purcell A, Buckley T, King J, Moyle W, Marshall A. ⁵⁵ | To examine the effectiveness of topical analgesic and topical local anaesthetic for reducing pain in chronic leg ulcers | Topical local anaesthetics lidocaine or prilocaine and topical analgesic agents such as ketamine, nonsteroidal anti-inflammatory drugs, opioids, tricyclic antidepressants (amitriptyline), or capsaicin on participants with chronic leg ulcers | MEDLINE, EMBASE, CINAHL, Joanna Briggs Institute, PubMed, and the Cochrane Library, and hand searched international consensus documents and position statements | 19x RCTs, 1x quasi-experimental study, 2x crossover studies and 1x retrospective observational medical record review | Patients with chronic leg ulcers with wound related pain | 23 | January 1990 to August 2019 | NRS, VAS, VRS, and numeric box scale. For topical anaesthetic agents studies - the visual analogue scale was the predominant pain assessment tool | Coping strategies were employed to reduce pain and wound prevention. The level of pain prevented physical activities. Activities of daily living such as preparing meals or carrying out housework were impeded for the majority of patients. This study revealed psycho-social, mobility, economical problems of having chronic ulcerations and the treatment of the wounds The findings related to topical analgesic and topical local anaesthetic agents for the relief of chronic leg ulcer pain indicate that topical agents (except for morphine gel) are effective. The only topical formulations used as primary dressings for chronic leg ulcer pain have been ibuprofen foam and morphine gel, and rarely, lidocaine/prilocaine cream. | UK, Germany, New Zealand, US, Brazil |

| Authors, Year | Aim / Purpose of Systematic Review/ Outcomes | Interventions / phenomena of interest | Databases sourced and searched | Types of Studies Included | Participant details | No. of studies included | Date range of database searching | Pain assessment tools used | Summary of results / findings | Context / Setting / Geographical location of studies included |
|--|---|---|--------------------------------|---|---|-------------------------|----------------------------------|---|--|--|
| Gutierrez Y, Pourali S, Kohn A, Jones M, Rajkumar J, Armstrong A ⁵⁷ | To synthesize and interpret the evidence on topical opioid use for skin diseases and to discuss their practical use in dermatology. Systematic review | Topical opioids included in this review were topical morphine and diamorphine. Common formulations consisted of 0.2–10 mg of opioid compounded with hydrogel or IntraSite gel. Investigated the frequency of application for pain management in skin diseases | PubMed, Embase, and Cochrane | 11x RCT, 2x non randomized interventional studies, 1x retrospective cohort study Specifically studies on chronic ulcers: 6x RCT, 2x non-RCT, 1x retrospective cohort study | n=263 chronic ulcerative lesions (pressure ulcers n = 4 studies, venous and/or arterial ulcers n = 3 studies, or ulcers of various aetiologies (n=2 studies) which included traumatic, malignant, cellulitis, and necrotic angiodermatitis. Burns (n=2 studies) oral lichen planus (n=1 study), photodynamic therapy associated pain (n=1 study). Split-thickness skin grafts n=1 study | 14 | 1980–2021 | Pain intensity scores measured by the VAS, or the NRS were the primary outcome measures in 10 of 12 included studies. Other assessment tools included the Brief Pain Inventory-Pain Scale (BPI-PS) and the Likert scale from 1–4 (none, mild, moderate, severe, overwhelming) | Topical opioid use in individuals with pressure ulcers has the potential of minimizing the use of systemic opioids. However no statistical improvement in pain was found for venous or arterial ulcers nor in the various aetiologies ulcer category when topical opioid was used. Literature is mixed regarding the efficacy of topical opioid use in non-pressure ulcers, oral lichen planus, PDT, and STSG, | Inpatient palliative care, India. Outpatient dermatology and primary care clinics, Sweden, Department of Dermatology, Germany Outpatient dermatology clinic, Netherlands, Inpatient oncology department, Italy, Inpatient dermatology department, France, Hospice Care, UK, Inpatient Hospice, UK, Outpatient university hospital, Germany, University Hospital Burn Center, Sweden. Outpatient Dermatology Department, Denmark, Emergency department, United Kingdom. Inpatient Burn Center, US |

| Authors, Year | Aim / Purpose of Systematic Review/ Outcomes | Interventions / phenomena of interest | Databases sourced and searched | Types of Studies Included | Participant details | No. of studies included | Date range of database searching | Pain assessment tools used | Summary of results / findings | Context / Setting / Geographical location of studies included |
|--|--|---|--|--|---------------------|-------------------------|----------------------------------|---|--|--|
| Da Costa Ferreira S, Sema González C, Thum M, Da Costa Faresin A, Woo, De Gouveia Santos V ⁶⁶ | To map and synthesise the existing literature on topical therapies for Malignant fungating wound (MFW) pain management and identify the existing gaps. This was a scoping review. | Topical therapies identified included analgesic drugs, antimicrobial substances, dressings, negative pressure therapy and cryotherapy | CINAHL (EBSCO), LILACS (VHL Regional Portal), Embase, Scopus, Web of Science, Medline (PubMed), Cochrane, NICE, JBI/SRIR, as well as unpublished studies on the Open Access Scientific Repository (Canada), Canadian Dissertation and Thesis Portal, Thesis Doctorates Database - Teso (Spain), CAPES Thesis Bank (Brazil), Google Scholar (including Textbooks and Congress Proceedings), and the European Thesis and Dissertation Database- Dart-E | Non systematic reviews, RCT, case studies, survey, control trials, systematic reviews, guidelines, cohorts | Cancer patients | 70 | No time limit was applied | Visual Analogue Scale, Numerical Verbal Scale, McGill's Questionnaire and the assessment by categories (no pain, weak, moderate and severe) | The topical therapies with positive results were lidocaine/prilocaine 2.5%, morphine gel 0.2% as analgesics, metronidazole 0.8% solution and polyhexamethylene biguanide (PHMB) with betaine 0.1% solution, octenidine solution, honey and silver as antimicrobials. The combination of topical therapies on the wound bed, periwound skin and the application of techniques of dressing change aiming at pain prevention can potentially improve the painful experience in people with MFWs | England, US, Portugal, Spain, Poland, Switzerland, Canada, France, Scotland, Australia, New Zealand, China, Brazil |

Appendix 3: Detailed Search Strategy for the Narrative Review for Pain Assessment Tools

Search Strategy (Medline)

| # | Searches | Results |
|----|---|---------|
| 1 | Pain Measurement/ | 94085 |
| 2 | “Surveys and Questionnaires”/ | 550039 |
| 3 | Nursing Assessment/ | 29092 |
| 4 | (pain adj2 assessment*).mp. | 11160 |
| 5 | (pain adj2 tool*).mp. | 1644 |
| 6 | (pain adj2 score*).mp. | 43975 |
| 7 | (pain adj2 questionnaire*).mp. | 6955 |
| 8 | (pain adj2 survey*).mp. | 1028 |
| 9 | (pain adj2 measure*).mp. | 102333 |
| 10 | (pain adj2 scale*).mp. | 20941 |
| 11 | (pain adj2 instrument*).mp. | 618 |
| 12 | (pain adj2 chart*).mp. | 188 |
| 13 | (pain adj2 appraisal*).mp. | 152 |
| 14 | (pain adj2 indicat*).mp. | 3628 |
| 15 | (pain adj2 self report*).mp. | 3860 |
| 16 | (pain adj2 check list*).mp. | 11 |
| 17 | 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 | 708670 |
| 18 | Pain/ | 148584 |
| 19 | Chronic Pain/ | 21136 |
| 20 | Nociceptive Pain/ | 957 |
| 21 | Pain Perception/ | 3127 |
| 22 | pain*.mp. | 917889 |
| 23 | 18 or 19 or 20 or 21 or 22 | 917889 |
| 24 | “Wounds and Injuries”/ | 81078 |
| 25 | Wound Healing/ | 104199 |
| 26 | Ulcer/ | 15184 |
| 27 | wound*.mp. | 439094 |
| 28 | ulcer*.mp. | 283841 |
| 29 | coloni?* wound*.mp. | 177 |
| 30 | contamin* wound*.mp. | 762 |

| # | Searches | Results |
|----|--|---------|
| 31 | infect* wound*.mp. | 3805 |
| 32 | coloni?* ulcer*.mp. | 426 |
| 33 | contamin* ulcer*.mp. | 4 |
| 34 | infect* ulcer*.mp. | 423 |
| 35 | 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 | 698112 |
| 36 | 23 and 35 | 45935 |
| 37 | 17 and 36 | 7193 |
| 38 | validate*.mp. | 475899 |
| 39 | validation.mp. | 348866 |
| 40 | validating.mp. | 23246 |
| 41 | 38 or 39 or 40 | 738100 |
| 42 | 37 and 41 | 246 |
| 43 | from 42 keep 3, 7, 16, 19-20, 29-31, 35... | 30 |
| 44 | limit 37 to (clinical trial, all or guideline or meta analysis or observational study or randomized controlled trial or “systematic review” or validation study) | 2856 |
| 45 | limit 44 to humans | 2807 |
| 46 | limit 45 to english language | 2691 |
| 47 | 46 not 42 | 2591 |
| 48 | exp Lower Extremity/ | 182887 |
| 49 | lower limb*.mp. | 61081 |
| 50 | lower extremit*.mp. | 79492 |
| 51 | 48 or 49 or 50 | 264009 |
| 52 | 47 not 51 | 2474 |
| 53 | from 52 keep 19, 31, 89, 155, 210, 299... | 19 |
| 54 | 43 or 53 | 49 |

Search Strategy (Embase)

| # | Searches | Results |
|----|---|---------|
| 1 | Pain Measurement/ | 10882 |
| 2 | "Surveys and Questionnaires"/ | 848888 |
| 3 | Nursing Assessment/ | 27433 |
| 4 | (pain adj2 assessment*).mp. | 102131 |
| 5 | (pain adj2 tool*).mp. | 2425 |
| 6 | (pain adj2 score*).mp. | 67675 |
| 7 | (pain adj2 questionnaire*).mp. | 11621 |
| 8 | (pain adj2 survey*).mp. | 1572 |
| 9 | (pain adj2 measure*).mp. | 30466 |
| 10 | (pain adj2 scale*).mp. | 32511 |
| 11 | (pain adj2 instrument*).mp. | 826 |
| 12 | (pain adj2 chart*).mp. | 302 |
| 13 | (pain adj2 appraisal*).mp. | 215 |
| 14 | (pain adj2 indicat*).mp. | 5432 |
| 15 | (pain adj2 self report*).mp. | 5347 |
| 16 | (pain adj2 check list*).mp. | 14 |
| 17 | 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 | 1038350 |
| 18 | Pain/ | 350156 |
| 19 | Chronic Pain/ | 73251 |
| 20 | Nociceptive Pain/ | 2158 |
| 21 | Pain Perception/ | 44477 |
| 22 | pain*.mp. | 1607118 |
| 23 | 18 or 19 or 20 or 21 or 22 | 1615978 |
| 24 | "Wounds and Injuries"/ | 175818 |
| 25 | Wound Healing/ | 136028 |
| 26 | Ulcer/ | 44390 |
| 27 | wound*.mp. | 436113 |
| 28 | ulcer*.mp. | 403196 |
| 29 | coloni?* wound*.mp. | 227 |
| 30 | contamin* wound*.mp. | 893 |
| 31 | infect* wound*.mp. | 4902 |

| # | Searches | Results |
|----|---|---------|
| 32 | coloni?* ulcer*.mp. | 668 |
| 33 | contamin* ulcer*.mp. | 10 |
| 34 | infect* ulcer*.mp. | 662 |
| 35 | 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 | 963441 |
| 36 | 23 and 35 | 113505 |
| 37 | 17 and 36 | 13377 |
| 38 | validate*.mp. | 696526 |
| 39 | validation.mp. | 526596 |
| 40 | validating.mp. | 32176 |
| 41 | 38 or 39 or 40 | 1065484 |
| 42 | 37 and 41 | 654 |
| 43 | limit 37 to (clinical trial, all or guideline or meta analysis or observational study or randomized controlled trial or "systematic review" or validation study) [Limit not valid in Embase; records were retained] | 3496 |
| 44 | limit 43 to humans | 3436 |
| 45 | limit 44 to english language | 3320 |
| 46 | 45 not 42 | 3219 |
| 47 | exp Lower Extremity/ | 458284 |
| 48 | lower limb*.mp. | 109390 |
| 49 | lower extremit*.mp. | 92100 |
| 50 | 47 or 48 or 49 | 545956 |
| 51 | 46 not 50 | 3040 |
| 52 | limit 1 to ("remove medline records" and embase database only) | 489 |
| 53 | limit 2 to ("remove medline records" and embase database only) | 132652 |
| 54 | limit 3 to ("remove medline records" and embase database only) | 146 |
| 55 | limit 4 to ("remove medline records" and embase database only) | 21037 |

| # | Searches | Results |
|----|---|---------|
| 56 | limit 5 to ("remove medline records" and embase database only) | 339 |
| 57 | limit 6 to ("remove medline records" and embase database only) | 9725 |
| 58 | limit 7 to ("remove medline records" and embase database only) | 1809 |
| 59 | limit 8 to ("remove medline records" and embase database only) | 195 |
| 60 | limit 9 to ("remove medline records" and embase database only) | 3270 |
| 61 | limit 10 to ("remove medline records" and embase database only) | 5261 |
| 62 | limit 11 to ("remove medline records" and embase database only) | 98 |
| 63 | limit 12 to ("remove medline records" and embase database only) | 34 |
| 64 | limit 13 to ("remove medline records" and embase database only) | 23 |
| 65 | limit 14 to ("remove medline records" and embase database only) | 754 |
| 66 | limit 15 to ("remove medline records" and embase database only) | 497 |
| 67 | limit 16 to ("remove medline records" and embase database only) | 3 |
| 68 | limit 17 to ("remove medline records" and embase database only) | 161237 |
| 69 | limit 18 to ("remove medline records" and embase database only) | 54401 |
| 70 | limit 19 to ("remove medline records" and embase database only) | 15690 |
| 71 | limit 20 to ("remove medline records" and embase database only) | 559 |
| 72 | limit 21 to ("remove medline records" and embase database only) | 7909 |
| 73 | limit 22 to ("remove medline records" and embase database only) | 329099 |
| 74 | limit 23 to ("remove medline records" and embase database only) | 330554 |

| # | Searches | Results |
|----|---|---------|
| 75 | limit 24 to ("remove medline records" and embase database only) | 32163 |
| 76 | limit 25 to ("remove medline records" and embase database only) | 25319 |
| 77 | limit 26 to ("remove medline records" and embase database only) | 7300 |
| 78 | limit 27 to ("remove medline records" and embase database only) | 79555 |
| 79 | limit 28 to ("remove medline records" and embase database only) | 82004 |
| 80 | limit 29 to ("remove medline records" and embase database only) | 33 |
| 81 | limit 30 to ("remove medline records" and embase database only) | 121 |
| 82 | limit 31 to ("remove medline records" and embase database only) | 892 |
| 83 | limit 32 to ("remove medline records" and embase database only) | 81 |
| 84 | limit 33 to ("remove medline records" and embase database only) | 2 |
| 85 | limit 34 to ("remove medline records" and embase database only) | 127 |
| 86 | limit 35 to ("remove medline records" and embase database only) | 183816 |
| 87 | limit 36 to ("remove medline records" and embase database only) | 25235 |
| 88 | limit 37 to ("remove medline records" and embase database only) | 2505 |
| 89 | limit 38 to ("remove medline records" and embase database only) | 95441 |
| 90 | limit 39 to ("remove medline records" and embase database only) | 92606 |
| 91 | limit 40 to ("remove medline records" and embase database only) | 4067 |
| 92 | limit 41 to ("remove medline records" and embase database only) | 158491 |
| 93 | limit 42 to ("remove medline records" and embase database only) | 88 |

| # | Searches | Results |
|-----|---|---------|
| 94 | limit 43 to ("remove medline records" and embase database only) | 635 |
| 95 | limit 44 to ("remove medline records" and embase database only) | 627 |
| 96 | limit 45 to ("remove medline records" and embase database only) | 573 |
| 97 | limit 46 to ("remove medline records" and embase database only) | 564 |
| 98 | limit 47 to ("remove medline records" and embase database only) | 58585 |
| 99 | limit 48 to ("remove medline records" and embase database only) | 19675 |
| 100 | limit 49 to ("remove medline records" and embase database only) | 14107 |
| 101 | limit 50 to ("remove medline records" and embase database only) | 78132 |
| 102 | limit 51 to ("remove medline records" and embase database only) | 537 |
| 103 | from 93 keep 21, 28, 43, 50-51, 62, 65... | 9 |
| 104 | from 102 keep 104, 337 | 2 |
| 105 | 103 or 104 | 11 |

| # | Searches | Results |
|----|---|---------|
| 12 | (pain adj2 instrument*).mp. | 219 |
| 13 | (pain adj2 chart*).mp. | 30 |
| 14 | (pain adj2 appraisal*).mp. | 151 |
| 15 | (pain adj2 indicat*).mp. | 1176 |
| 16 | (pain adj2 self report*).mp. | 1372 |
| 17 | (pain adj2 check list*).mp. | 9 |
| 18 | 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 | 529426 |
| 19 | Pain/ | 30348 |
| 20 | Chronic Pain/ | 15452 |
| 21 | Pain Perception/ | 11330 |
| 22 | pain*.mp. | 134458 |
| 23 | 19 or 20 or 21 or 22 | 134458 |
| 24 | exp Wounds/ | 1408 |
| 25 | wound*.mp. | 12840 |
| 26 | ulcer*.mp. | 4461 |
| 27 | coloni?* wound*.mp. | 9 |
| 28 | contamin* wound*.mp. | 2 |
| 29 | infect* wound*.mp. | 22 |
| 30 | infect* ulcer*.mp. | 1 |
| 31 | 24 or 25 or 26 or 27 or 28 or 29 or 30 | 17017 |
| 32 | 23 and 31 | 1885 |
| 33 | 18 and 32 | 378 |
| 34 | validate*.mp. | 70539 |
| 35 | validation.mp. | 59780 |
| 36 | validating.mp. | 7612 |
| 37 | 34 or 35 or 36 | 121327 |
| 38 | 33 and 37 | 29 |
| 39 | from 38 keep 4-5, 10 | 3 |
| 40 | from 33 keep 2, 29, 75, 89, 107, 119... | 11 |
| 41 | 39 or 40 | 13 |

Search Strategy (PsycINFO)

| # | Searches | Results |
|----|--------------------------------|---------|
| 1 | Pain Measurement/ | 2509 |
| 2 | Surveys/ | 13228 |
| 3 | exp Questionnaires/ | 24776 |
| 4 | exp Measurement/ | 506765 |
| 5 | (pain adj2 assessment*).mp. | 3528 |
| 6 | (pain adj2 tool*).mp. | 610 |
| 7 | (pain adj2 score*).mp. | 3059 |
| 8 | (pain adj2 questionnaire*).mp. | 5067 |
| 9 | (pain adj2 survey*).mp. | 596 |
| 10 | (pain adj2 measure*).mp. | 18969 |
| 11 | (pain adj2 scale*).mp. | 6645 |

Search Strategy (CINAHL)

| # | Query | Limiters/Expanders | Results |
|-----|---|--|-----------------------------|
| S17 | S15 AND S16 | Search modes - Boolean/ Phrase | 407 (16 Results Identified) |
| S16 | validate* OR validation OR validating | Search modes - Boolean/ Phrase | 493,631 |
| S15 | S11 AND S12 AND S13 | Limiters - English Language; Human Search modes - Boolean/ Phrase | 2,810 |
| S14 | S11 AND S12 AND S13 | Search modes - Boolean/ Phrase | 3,908 |
| S13 | S9 OR S10 | Search modes - Boolean/ Phrase | 166,340 |
| S12 | S7 OR S8 | Search modes - Boolean/ Phrase | 379,050 |
| S11 | S1 OR S2 OR S3 OR S4 OR S5 OR S6 | Search modes - Boolean/ Phrase | 777,963 |
| S10 | wound* OR ulcer* | Search modes - Boolean/ Phrase | 166,340 |
| S9 | (MH "Wounds and Injuries") OR (MH "Wounds, Chronic") OR (MH "Fungating Wounds") OR (MH "Wounds, Penetrating") OR (MH "Surgical Wound Dehiscence") | Search modes - Boolean/ Phrase | 36,209 |
| S8 | pain* | Search modes - Boolean/ Phrase | 379,050 |
| S7 | (MH "Pain") | Search modes - Boolean/ Phrase | 81,507 |
| S6 | (MH "Questionnaires") | Search modes - Boolean/ Phrase | 466,005 |
| S5 | (MH "Surveys") | Search modes - Boolean/ Phrase | 161,656 |
| S4 | pain assessment tool* OR pain scale* OR pain measue* or pain assessment* OR pain rating scale* OR pain questionnaire* OR pain survey* | Search modes - Boolean/ Phrase | 38,581 |
| S3 | (MH "McGill Pain Questionnaire") | Search modes - Boolean/ Phrase | 2,156 |
| S2 | (MH "Clinical Assessment Tools") | Search modes - Boolean/ Phrase | 194,500 |
| S1 | (MH "Pain Measurement") | Search modes - Boolean/ Phrase | 52,194 |

Appendix 4: Summary Table of Evidence for pain assessment tools (Narrative Review)

| Authors (year) | Country | Study purpose | Design | Sample characteristics (sample size, age, gender wound duration) | Wound type | Data collection | Type of pain measurement/report | Results | Main finding |
|--|---------|--|-----------------------|---|--|--|--|--|--|
| Dallam L, Smyth C, Jackson BS, Kirinsky R, O'Dell C, Rooney J, Bacillo C, Amella E, Ferrara L, Freeman K ¹⁴ | US | To determine the perceived intensity and patterns of pressure ulcer pain in hospitalised patients. | Cross sectional study | N = 132 59% female Mean age 71.4 (SD 16.4) | Pressure ulcer stage 1-4 | | VAS (0-10) Faces Pain Rating scale. | VAS Pain scores significantly and inversely correlated with age (r=-0.36, P<0.02) and positively correlated with maximum pain intensity assessment. FFS (r= 0.92, p<0.01). The localised VAS to pressure ulcer sites significantly correlated with Max pressure ulcer stage (r=0.37, p<0.01) | Patients with pressure ulcers have wound related pain, and that this condition is frequently ignored untreated or not treated at all. Evaluation of pain by means of the VAS or FFS reveals that even cognitively impaired patients will express pressure ulcer related or generalised pain |
| Noonan L & Burge S ⁷¹ | UK | To employ validated techniques to measure and characterise the pain associated with leg ulceration of defined causes | | n=51 Females 57% VLU duration mean 5.7 yrs (median 1.5yrs) Arterial mean 2.3yrs (median 1.0yrs) Arterial/Venous (AV) ulcers mean 2.8yrs (median 1.0yr) Microvascular ulcers (MV) mean 0.6 years (median 0.5yr) | Leg ulcers: VLU n=38 arterial ulcers n=6 AV n=3 MV n=4 | Structured questionnaire. Administered by research nurse at leg ulcer clinic | VRS VAS SF-McGill Questionnaire COOP Chart System | Pain mean score: VLU = 5.88 Arterial/MV/AV 7.23 GoL: VLU 2.89/5, arterial 3.50/5, AV/MV 3.14/5 VLUs are painful. Although pain scores are greater in arterial ulcers, most patients with VLUs suffer at least moderate pain. Night pain disturbed sleep in 73% and pain affected mood in more than 50%. Dressing changes exacerbated pain. | Unidimensional rating scales fail to reflect the complexity of pain. |

| Authors (year) | Country | Study purpose | Design | Sample characteristics (sample size, age, gender wound duration) | Wound type | Data collection | Type of pain measurement/report | Results | Main finding |
|---|---------|---|--------|--|---------------------------------------|--|--|--|--|
| Walters SJ, Morrell CJ, Dixon S ⁹¹ | UK | To compare the performance of four Health related Quality of Life instruments in measuring HRQoL in patients with venous leg ulcers, in terms of their discriminative and evaluative properties | Survey | There was a good 86% response rate (200/233) at three months to the postal questionnaire There was a 67% response rate (156/233) at 12 months to the postal questionnaire. Median age 75 yrs Females 66.5% Median ulcer duration seven years | VLU below the knee including the foot | Baseline: self-completed questionnaire Demographics completed by interview Postal questionnaires containing the four HRQoL instruments were issued to all patients at 12 weeks, and to all surviving patients one year after recruitment | MOS 36-Item Short-Form Health Survey (SF-36); EuroQoL (EQ); Short Form McGill Pain Questionnaire (SF-MPQ) Frenchay Activities Index (FAI). | The SF-MPQ had poorer discriminative properties than the other three instruments and was not able to distinguish between the different patient groups in relation to age and ulcer duration Or between the different patient groups (at initial assessment) in relation to age, mobility and ulcer size For the short term (3-month follow-up), the SF-MPQ appears to have good evaluative properties None of the other tools were sensitive enough (all having small SRMs) to detect the condition-specific changes in health experienced by the patients and could not differentiate between healed and not healed groups of patients Over the longer 12-month period of follow-up more dimensions (on the SF-36 and EQ) were shown to be responsive to the ulcer healing. The FAI had poorer evaluative properties than the other three instruments and did not appear to be very sensitive at detecting differences in changes in HRQoL over time between patients whose ulcer had healed or not | The development and validation of a condition-specific tool for measuring improvement in patients' health, as defined by the patients themselves, would better serve the purpose of discriminating between positive changes attributable to the provision of leg ulcer care and co-existing poor general health The Chronic Venous Insufficiency Questionnaire (CIVIQ) was found to have good discriminative and evaluative properties in patients with venous insufficiency and may prove suitable for measuring changes in quality of life in patients with venous leg ulcers |

| Authors (year) | Country | Study purpose | Design | Sample characteristics (sample size, age, gender, wound duration) | Wound type | Data collection | Type of pain measurement/report | Results | Main finding |
|---|---------|--|---|---|----------------|---|--|--|--|
| Freeman K ⁶⁵ | US | To better understand the statistical properties of the Faces Rating Scale (FRS) so it can be used appropriately in clinical settings To describe the mathematical relationship between the VAS and the FRS when they are used to quantify pressure ulcer pain in hospitalized elderly patient | Secondary data analyses were performed as part of a cross-sectional study | | Pressure ulcer | | The VAS used was a 0 to 100 mm horizontal line demonstrated to have ratio scale properties with high validity and reproducibility, and the FRS used was six faces ordered horizontally from smiling to crying, labelled 0 to 5 beneath each face, respectively | The nonlinear relationship indicated high reliability between VAS and FRS for pain assessment in populations with diminished verbal and abstract thinking abilities. | A Faces Rating Scale is a simple measure of assessing pain before and after wound care. The Faces Rating Scale is especially helpful in patients who cannot verbalize their distress |
| Nemeth KA, Graham ID, Harrison MB ⁶⁶ | Canada | To identify and compare the psychometric, clinical sensibility, and pain-specific properties of leg ulcer pain assessment tools for use as a guide for clinicians and researchers | Review and appraisal of the literature | Not applicable | Leg ulcers | Databases used: (CINAHL), Psychology/Sociology (SOCFILE), and Medical Literature Analysis and Retrieval System Online (MEDLINE) | The 54 pain assessment tools identified Five tools met all the inclusion criteria and were subjected to the appraisal process: Pain ruler Numerical Rating Scale Visual Analog Scale Verbal Rating Scale Short Form -McGill Pain Questionnaire | The most commonly unmet criteria were "tool used in different diseases/pain-inducing interventions in adults" (n=41) and "measures quality and/or intensity of pain only" (n=28) | The appraisal revealed that each tool met the psychometric, clinical sensibility, and pain-specific criteria to varying degrees; however, use with individuals with leg ulcers has been limited. No evidence indicates that any of the five tools have been specifically evaluated psychometrically with the leg ulcer population. However, they show promise because they have demonstrated reliability and validity with other populations, despite limited use in individuals with leg ulcers. |

| Authors (year) | Country | Study purpose | Design | Sample characteristics (sample size, age, gender, wound duration) | Wound type | Data collection | Type of pain measurement/report | Results | Main finding |
|---|---------|--|------------------------|---|-----------------------|--|---|--|---|
| Roth RS, Lowery JC, Hamill JB ³⁴ | US | To examine pain experience among patients with chronic wounds, and determine the relation of wound-related pain to wound stage, affective distress, depressive symptoms, and pain catastrophizing. | Cross-sectional study. | n=69 with spinal cord injuries. All participants were men n=19 who experienced pain associated with their wounds Average age: 59 Average duration of wounds 4.1 months (SD = 4.3 months). | Mixed chronic wounds. | Participants were examined by both a physician and the nurse coordinator as part of the assessment protocol for monitoring wound status. Subjects were seen for a maximum of six visits to monitor changes in their wound status. Pain data were obtained during their first visit . | Numerical Pain Rating Scale, McGill Pain Questionnaire Mood assessment: Brief Symptom Inventory, Center for Epidemiologic Studies Depression Scale Pain catastrophizing: catastrophizing scale of the Coping Strategies Questionnaire. | Relative insensitivity of the single pain intensity measure NPRS compared with the MPQ for assessing chronic wound pain. NPRS did correlate significantly with pain catastrophizing, but it did not relate to any of the other pain rating measures. The NPRS was unrelated to measures of depression and distress, an anticipated association that has been commonly observed for patients with chronic pain. The NPRS did not discriminate changes in pain severity across stages of wound severity. A pattern of association was found of pain catastrophizing with pain experience, affective distress, and depressive symptoms. Data suggest that examining for the presence of catastrophizing and providing intervention strategies for its modification may be particularly beneficial for patients being treated for chronic wound pain. | The McGill Pain Questionnaire was more sensitive to pain experience than a single rating of pain intensity. Wound stage was positively related to severity of pain. Pain catastrophizing was positively related to pain intensity and higher levels of affective distress and depressive symptoms. Patients with chronic wound pain present a profile of emotional distress and its relation to maladaptive pain coping that is consistent with the available literature drawn from other populations with pain. |

| Authors (year) | Country | Study purpose | Design | Sample characteristics (sample size, age, gender, wound duration) | Wound type | Data collection | Type of pain measurement/report | Results | Main finding |
|-------------------------|---------|---|----------------------|---|----------------|--|--|--|---|
| Barrett S ⁵⁵ | UK | To evaluate Heal Not Hurt pain assessment and management tool for during dressing changes | Narrative evaluation | Not specified. Evaluation implemented by district nursing team. | Not specified | Not specified No data collection or analysis provided | Heal Not Hurt wound pain assessment and recording tool Included: Faces Rating Scale, Verbal Scale (none, very mild, mild, moderate, severe, very severe) VAS NRS | The tool improved the district nurses level of understanding of both the patients' needs and the way that they had managed pain. | Overall the tools improved skill in pain management and improved documentation |
| White RJ ⁶⁸ | UK | Considers interventions and procedures for managing pain in patients with chronic wounds. | Narrative | Not applicable | Chronic wounds | Not applicable | Key elements of pain assessment include: pain type, nociceptive, neuropathic or mixed; duration; severity; impact of pain on the patient; relief rating; assessment of post-analgesia scores; and identification of treatment-related adverse effects to reduce their impact. | Not applicable | No single pain measuring scale is suitable for all patients; choice is dependent on an individual's need. Once chosen the same scale should be used for subsequent assessments. |

| Authors (year) | Country | Study purpose | Design | Sample characteristics (sample size, age, gender, wound duration) | Wound type | Data collection | Type of pain measurement/report | Results | Main finding |
|--|---------|--|---|---|--|--|--|--|--|
| Maida V & Ennis Mand Kuziunsky C ⁹⁶ | Canada | To formulate a patient-rated assessment tool that facilitates the measurement of pain and polysymptom distress directly related to all classes of wounds | A prospective observational study derived from a sequential case series of patients with advanced illness was carried out to determine the most common symptoms associated with wounds. to develop and pilot a patient-scored assessment tool | Phase 1: n=531 Phase 2 n = 83 | Pressure ulcers, traumatic wounds, malignant wounds, DFU ostomies, arterial ulcers, iatrogenic wounds, infected wounds | Phase 1: patients were given a list of 9 symptoms and were asked to rank their 3 most severe symptoms. Phase 2: TSAS-W was created by applying 11-point NRSs to the most common wound-related symptoms reported by patients in the initial phase of the study | Toronto Symptom Assessment System for Wounds (TSAS-W) 11 point NRS for all symptoms | Pain with dressing and/or debridement (mean baseline 3.88) mean score 7 days later 3.00) Pain between dressing and/or debridement (3.44 and 2.78) | There is a significant need for assessment tools that measure wound-related pain and symptom issues as reflected by their paucity in the peer-reviewed literature. The availability of these tools, instruments, or questionnaires may serve to promote improvements in clinical assessment and result in improved outcomes, especially when they are completed by the patient. Furthermore, symptom measurement must be carried out regularly and serially. In addition, such tools will also facilitate clinical audit, as well as research into wound-related pain and symptom management |
| Woo K & Sibbald RG ⁹⁷ | Canada | To validate an organized pain management approach using the Wound Associated Pain model in subjects with chronic leg and foot ulcers | A prospective cohort study that documented pain in chronic wound subjects over a 4-week period | A total of 111 subjects with chronic leg and foot ulcers were recruited from the community and ambulatory wound care clinics male (60.4%) and their average age was 66 years (range, 33 -95 years) | Leg ulcers and foot ulcers | | NRS is a comparatively simple instrument that is easy to administer and score. It has been used in a variety of patient populations including geriatric subjects The NRS scores are significantly related to the pain thermometer (r 0.91), the vertical visual analogue scale (r 0.92), and the verbal descriptor scale (r 0.91) in elderly patients The NRS has been shown to be more reliable than visual analogue scales, particularly among subjects with a lower educational level | More than 60% of our subjects reported pain associated with their lower extremity wounds and almost half (45.6%) experienced severe pain (NRS pain scores 7) Significant reductions in pain intensity were achieved by correcting the wound cause, addressing patient-centred concerns, using pharmacological agents to relieve pain, and applying atraumatic dressings | The WAP model was developed to integrate principles of wound pain assessment and management into principles of wound bed preparation. A comprehensive patient assessment can improve chronic leg and foot ulcer wound-related pain and healing rates |

| Authors (year) | Country | Study purpose | Design | Sample characteristics (sample size, age, gender, wound duration) | Wound type | Data collection | Type of pain measurement/report | Results | Main finding |
|-------------------------|-----------|--|------------------------------------|---|--|---|---|--|---|
| Woo K ⁵² | Canada | To explore the relationship of attachment style and pain during dressing change in an older population In particular the study focussed on the role that anxiety, anticipatory self-reported pain, and behavioural expression of pain play in these relationships | Cross-sectional study | n = 96 Males n= 38 Wound duration Mean 8.38 months (SD14.08m) | Leg ulcers: Venous 78.1%, Pressure ulcer 8.3% Mixed arterio-venous 7.3% | Questionnaire Pain was evaluated before dressing change (T1), at dressing removal (T2), at cleansing (T3), with dressing reapplication (T4) and after dressing change (T5) | NRS, SF-MPQ, Pain Assessment in Advanced Dementia scale (PAINAD) Relationship Scales Questionnaire (RSQ) Shortened Anxiety Scale (SAS) Pressure Ulcer Scale for Healing (PUSH) | Elderly subjects experienced more pain during dressing change than at baseline Attachment needs (anxiety over self-worth and closeness to others) continue to exert a tremendous influence on older people living with chronic pain Patients who expressed high levels of attachment anxiety and avoidance reported heightened anxiety, increased anticipation of pain, and more intense pain during dressing change in comparison to secure individuals | This study of older adults has provided empirical evidence to support the influence of attachment on anticipatory pain, anxiety and experienced pain at dressing change Attachment anxiety and avoidance were critical to understanding how one reacts to threat, regulates negative emotions, and interprets a physiological symptom (pain) |
| Frescos N ⁵¹ | Australia | To determine if a validated and holistic pain assessment instrument is available for use in the primary care setting to assess wound pain in chronic lower limb wounds | A scoping review of the literature | N/A | Chronic lower limb wounds | MEDLINE, CINAHL, EMBASE and PsycINFO | Common tools: Pain ruler, NRS VAS VRS SF-MGQ Numeric Pain Scale Faces Scales Other tools: Diabetes Foot Ulcer Scale Short SF-12 Brief Pain Inventory | Four common generic pain assessment tools used by health care practitioners were found: the NRS, VAS, VRS and SF-MPQ. These tools were appraised and justified to offer one pain assessment tool that could be useful for leg ulcer | Although four common pain measurement tools were identified to be suitable for wound pain, current evidence is insufficient to recommend one pain assessment tool that is suitable for chronic lower limb wounds |

| Authors (year) | Country | Study purpose | Design | Sample characteristics (sample size, age, gender, wound duration) | Wound type | Data collection | Type of pain measurement/report | Results | Main finding |
|--|------------------|--|---------------------------------|---|-----------------|---|--|---|--|
| Rutherford C, Nixon JE, Brown JM, Briggs M, Horton M ⁷³ | Australia/ UK | To investigate whether the Leeds Assessment of Neuropathic Symptoms and Signs scale (LANSS) is suitable for use as an outcome measure in people with PUs | Psychometric and Rasch analyses | n=709, Age mean = 76 (15.3) Female 59.1% | Pressure Ulcers | Hospital in patients and Community outpatient services: Patient was assessed by asking 2 pain screening questions. Those reporting pain then were assessed with VAS and LANSS | VAS of 0-10 LANSS Pain Scale The LANSS contains five patient-reported symptom items and two clinical sensory testing items associated with neuropathic pain | Findings support unidimensional scale But not supported for internal construct validity For LANSS, there was low to moderate item correlations. Chi Square (df = 28) 55.546, p = 0.002, inter - item correlations (mean 0.117 and range from 0.063 to 0.415) and low Cronbach's alpha (0.549) and Person Separation Index (0.334) | The LANSS is not suitable as an outcome measure of pressure ulcer-related neuropathic pain as it did not meet requirements for reliable and valid measurement in this population |
| Kogure T, Sumitani M, Abe H, Hozumi J, Inoue R, Miitani K, et al ⁷³ | Japan | Examined the discriminant validity of the classification by providing a list of distinct pain quality descriptors in the MPQ to dichotomize pain into nociceptive or neuropathic | Cross sectional study | N =489, Divided into neuropathic pain group and nociceptive pain group based on diagnoses. Post revascularisation (n=18) | | | Categorized ischemic ulcer pain into nociceptive/inflammatory pain (NocP) or neuropathic pain (NeP), on the basis of patients' descriptions of their pain using the MPQ Post revascularisation Approximately half of the patients with ischemic ulcer pain were classified as NeP before revascularization, and 70% who had residual pain after revascularization were classified as NeP | Among these patients complaining of NeP after revascularization, the NocP complaints by more than a half of the patients before revascularization turned into complaints of NeP after revascularization | Confirmed that ischemic ulcer pain has both components of NocP and NeP |

| Authors (year) | Country | Study purpose | Design | Sample characteristics (sample size, age, gender, wound duration) | Wound type | Data collection | Type of pain measurement/report | Results | Main finding |
|-------------------------|---------|--|--|---|------------------------|-----------------|--|---------|---|
| Newbern S ⁸⁶ | Alaska | To describe the experiences and perceptions of pain and pain management for patients with chronic wounds related to lower extremity vascular disease. The goals of this study are to clinically appraise the evidence for the efficacy of existing assessment practices, identify barriers to providing holistic patient care with pain management, and acknowledge pain impact on QoL | An integrative literature review using CINAHL, Google Scholar, PubMed, written journals, and scholarly textbooks was performed | | Lower extremity wounds | | Medical outcome study, pain measures, Modified EQ-5D Questionnaire, Brief Pain Inventory, The Neuropathic Pain Scale, Neuropathic Pain symptom inventory, The Diabetic Peripheral Neuropathic Pain Impact Measure, The Short-Form McGill Pain Questionnaire, Numeric Pain Scale, SF-36 Health Status Questionnaire, Brockopp-Warden Pain Knowledge/Bias Questionnaire, Hospital Depression and Anxiety Scale | | Lack of a validated pain and QoL assessment tool for patients experiencing diabetic foot ulcers or chronic lower-extremity wounds is a barrier to appropriate pain management There is a need for wound pain validation and further studies related to holistic pain identification including the psychosocial aspects of pain Single-question pain assessment instruments may not be appropriate for evaluating neuropathic pain and may lead the clinical provider to undertreat pain and associated QoL symptoms |

| Authors (year) | Country | Study purpose | Design | Sample characteristics (sample size, age, gender, wound duration) | Wound type | Data collection | Type of pain measurement/report | Results | Main finding |
|--|-----------|--|--|---|---------------------|---|---|--|---|
| Frescos N ⁸⁹ | Australia | To determine how practitioners assess wound related pain, including the types of assessment tools used and frequency of assessment | Survey Descriptive study that used convenience sampling | N = 1189 Health care professionals involved in wound care. Nurses (89%), podiatrist (7%) and others (4%) | Chronic wounds | Self-administered questionnaire mailed out to health practitioners' who were members of a wound association | Numerical analogue scale (NAS) VRS VAS Faces Rating Scale Abbey Scale | A total of 63% (n = 738) of practitioners indicated that they used a validated pain assessment tool. The most common validated pain assessment tool used by all 3 categories of professions was the numerical analogue scale (n = 524, 46%), followed by the verbal rating scale (n = 328, 28%). When comparing the use of validated tools between the professions, nurses were more likely to use the visual analogue scale ($\chi^2 = 7.82$, $df = 2$, $P = .020$), faces scale ($\chi^2 = 7.99$, $df = 2$, $P = .018$), and numerical analogue scale ($\chi^2 = 12.46$, $df = 2$, $P = .002$) compared with the other | A variety of assessment methods were used to gather information about the patients' pain, and the process used to identify pain was not uniform among practitioners. The most common approach in identifying and assessing pain by all categories of health professionals was talking to the patient and asking the patient to give a self-report rating of their pain. This study suggests that health care practitioners use various methods of identifying or assessing wound pain |
| Ren Y, Luo X, Xie C, Zhang P, Meng M, Song H ⁹⁰ | China | To determine the gap between evidence-based criteria and current clinical practice regarding assessment and management of dressing-related pain To standardize strategies for assessment and management of dressing-related pain by developing an education program To improve diabetic foot nurses' compliance with evidence-based criteria regarding dressing related pain assessment and management | Clinical audit | n= 50 patients n = 15 nursing staff | Diabetic foot ulcer | Audit tool with six criteria to measure the compliance rates with best practice Before and after implementation of training of nurses on how to assess and when to assess pain Implemented pain management survey and intervention strategy | VAS C-PAINAD scale for patients with dementia | Barriers identified: Lack of standardised pain assessment tools Nurses do not have enough time to assess pain; Absence of education materials for patients No formal education regarding pain assessment and management for nurses Improvements were observed after training. | Improved compliance with strategies to implement best practice was the key to success to improving pain assessment and management by nurses |

| Authors (year) | Country | Study purpose | Design | Sample characteristics (sample size, age, gender, wound duration) | Wound type | Data collection | Type of pain measurement/report | Results | Main finding |
|-------------------------|---------|--|--------------------------|---|---|-----------------|---|---|--------------|
| Jenkins S ³⁷ | UK | Review of what is required in the assessment of pain in individuals with chronic wounds. | Review of the literature | Not applicable | Chronic wounds, aetiologies not specified | Not applicable | <p>Pain Quantity: NPRS, VAS, VRS</p> <p>Physical functioning: Brief Pain Inventory</p> <p>Emotional Functioning: Beck Depression Inventory (BDI), Centre for Epidemiologic Studies Depression Scale (CESD), Hospital Anxiety and Depression Scale (HADS), Short Form MOS-36 (SF36) Profile of Mood states (POMS), Pain Catastrophising Scale</p> <p>Patient Health Questionnaire – 2, Pain Self Efficacy Questionnaire (PSEQ)</p> <p>Quality of Life: EuroQol 5D</p> <p>Patient reported global rating: Patient Global Impression of Change</p> | <p>A biopsychosocial assessment is required through discussion and use of assessment tools. Validated tools are available for the assessment of pain quantity, physical functioning, emotional functioning and a person's global rating. Due to the lack of validated pain assessment tools for those with chronic wounds, these validated chronic pain tools should be considered. Working with a local pain service can help identify appropriate tools and those that are used locally</p> | |

| Authors (year) | Country | Study purpose | Design | Sample characteristics (sample size, age, gender, wound duration) | Wound type | Data collection | Type of pain measurement/report | Results | Main finding |
|---|---------|--|----------------------|---|------------|-----------------|---|---------|--|
| Leren L, Johansen E, Eide H, Falk R, Juvet L, Ljoså T ⁸⁸ | Norway | To describe the prevalence of wound related a background pain in CVLUs, describe characteristic of the wound related background pain | SR and meta-analysis | Mean age of patients 50.3-74.6years | CVLUs | Databases | NRS (0-10) 12 studies VAS 10 studies VRS 6 studies SF-MPQ 3 studies DN4 1 study Medical Outcome Scale 1 study BPI 1 study (pain interference) Non validated tool 2 studies | | The majority of persons with CVLU experience wound-related background pain, reporting mild to moderate pain intensity. Because of the poor quality of the assessment and reporting of pain, it is likely that the research available underestimates the severity of wound pain and provides an inaccurate and simplified clinical picture Encourage future studies to adhere to standardised methods for collecting and presenting data on wound and pain characteristics |

| Authors (year) | Country | Study purpose | Design | Sample characteristics (sample size, age, gender, wound duration) | Wound type | Data collection | Type of pain measurement/report | Results | Main finding |
|--|---------|---|--|---|---|--|---|--|--|
| Leren L, Eide H, Johansen EA, Jelnes R, Ljoså TM (100) | Norway | To explore and describe characteristics of ulcer related background pain and pain management as reported by persons with CLUs | A descriptive analysis of cross-sectional data | Study sample was selected from a larger sample of persons with CLUs. (n=121) The mean age of participants was 74.4 years (SD 12.75), and 53.7% were female. A total of 39.7% were living alone, and 87.5% were not working | Chronic leg ulcer ankle or foot venous, DFU, traumatic arterial and other | Data were gathered with an initial screening interview, and a clinical examination at the wound outpatient clinic, as well as a self-report questionnaire filled in at home within 24 hours after the hospital visit | SF-MPQ was used to assess qualities of present ulcer related background pain BPI was used to provide information about the location, intensity, treatment, and interference of ulcer related pain on function in the last 24 hours | Ulcer pain intensity: The mean average pain intensity was 4.5 (SD 2.56) (CI 95% 4.0-5.0), and the mean worst pain intensity was 4.9 (SD 2.88) (CI 95% 4.4-5.5) (0-10 NRS). Mean present pain intensity was 38.65 mm (SD 27.23) (0-100 VAS) Pain interfered mostly with general activity (mean 4.3), sleep (mean 4.1), and walking ability (mean 4.0) (0-10 NRS). The average activity pain interference (WAW) was 4.1 (SD 2.8), and the average affective pain interference (REM) was 3.1 (SD 2.7) Ulcer pain qualities: The mean score on the sensory sub-scale of SF-MPQ was 6.95 (SD 6.66). The most frequently reported sensory descriptors were 'tender' (50.4%), 'stabbing' (49.6%), 'aching' (46.3%), and 'hot burning' (45.5%). On the affective sub-scale, the mean score was 1.36 (SD 2.19). The most frequently reported affective descriptor was 'tiring-exhausting' (32.2%) The majority stated that the ulcer related pain was intermittent (71.1%). None reported that the pain was stable | Ulcer related background pain is a significant and interfering problem. Over 60% of the participants reported moderate to severe pain intensity and that pain interfered with daily function It is important to conduct a thorough pain assessment in all persons presenting with CLUs, and especially in all persons reporting ulcer related background pain, to provide effective pain management |

Appendix 5: Summary of characteristics of the systematic reviews of physical therapies

| Authors (year) | Aim/purpose of systematic review/outcomes | Interventions/phenomena of interest | Databases sourced and searched | Types of studies included | Participant details | Number of studies included | Date range of database searching | Summary of results/findings | Context/setting/geographical location of studies included |
|--|---|--|---|---|--|--|----------------------------------|--|---|
| Yim E, Kirsner RS, Gailey RS, Mandel DW, Chen SC, Tomic-Canic M ¹⁸ | To evaluate the effect of physical therapy on healing and QoL outcomes in patients with VLLUs | Walking, standing heel-raises, tip-toe exercise, use of a treadmill, cycling, use of elastic resistance bands Supervision consisted of a physical therapist, a physical therapy assistant, a nurse or an exercise physiologist | PubMed (MEDLINE), CINAHL, and Cochrane databases | RCTs Single-arm cohort studies | Patients with open or healed VLLUs | 10 | Searched in April 2014 | Only two studies measured QoL and found no change in QoL after physical exercise They discussed that physical exercise has an effect on QoL and that pain was the most frequently identified factor affecting QoL In one study pain was reduced | Not indicated |
| Dymarek R, Haliski T, Ptaszkowski K, Slupska L, Rosinczuk J, Taradaj J ³⁶ | To evaluate the effectiveness of ESWT in wound healing | Extracorporeal shock wave (ESWT) using used low or medium energy, focused or defocused generator heads (energy range 0.03 to 0.25 mJ/mm ² ; usually 0.1 mJ/mm ²), and electrohydraulic or electromagnetic sources | MEDLINE, PubMed, Scopus, EBSCOhost, and PEDro databases | RCTs 7 studies Clinical controlled study 1 study Prospective clinical trials 3 studies Clinical case reports 2 studies | Patients with DFU, PU, chronic DFU, PU, VLU, and AIU (arterial insufficiency ulcer) wounds as well as acute wounds involving BW (Burn wound), TW (trauma wound), and SW (post-surgical wound) resulting from CABG or STSG procedures | 13 primary studies 2 systematic reviews | 2000 –2013 | The results of this study show ESWT can be characterized as a non-invasive, painless, and safe physical treatment modality that seems beneficial in healing soft tissue wounds It was found that ESWT as an anti-inflammatory treatment has effect on reepithelialisation, enhancing tissue granulation, improving blood flow perfusion and angiogenesis, reducing necrotic tissue and reducing time of total wound treatment | Not indicated |

| Authors (year) | Aim/purpose of systematic review/outcomes | Interventions/phenomena of interest | Databases sourced and searched | Types of studies included | Participant details | Number of studies included | Date range of database searching | Summary of results/findings | Context/setting/geographical location of studies included |
|---|--|--|---|--|---|---|----------------------------------|---|--|
| Ramundo J & Gray M ²⁴ | To determine whether ultrasonic mist therapy effectively removes necrotic debris from the bed of chronic wounds and promotes wound healing | Ultrasonic mist therapy, compared to other debridement | MEDLINE and CINAHL and Cochrane Database for Systematic Reviews | Prospective studies that compared ultrasonic mist debridement to any other debridement technique, to a sham device, or to no debridement were included | One study: adults with diabetes mellitus and Wagner grade 1 or 2 diabetic foot ulcers located on the plantar surface | No studies were identified that evaluated the efficacy of the direct contact of the ultrasonic mist therapy 2 RCTs found for necrotic tissue (1 single site, parallel group RCT, 1 double blind RCT) | January 1996 to February 2008 | According to the study this is a debridement method that reduces the necrotic tissue Procedural pain, when reported, has been successfully addressed with topical analgesia Clinical experience suggests that the need for pain management tends to diminish with subsequent treatments | Mentions one study that was conducted in the US and Canada |
| Chang YR, Perry J, Cross K ¹²⁶ | To review clinical evidence on the use of low frequency ultrasonic debridement as adjunctive therapy in chronic wounds | Comparison of low frequency ultrasound debridement with other debridement modalities | Ovid MEDLINE, Ovid EMBASE, the Cochrane Central Register of Controlled Trials, Agency for Healthcare Research & Quality, and Google Scholar | Retrospective case study, Single arm prospective study | Participants wound aetiology included burn wounds, surgical/trauma wounds, diabetic foot ulcers, pressure ulcers, arterial/venous insufficiency | 25 studies, RCT 8 studies | 2000 to 2017 | In relation to pain, ultrasound therapy is generally considered painless in contrary to sharp and mechanical debridement techniques. Treatment with MIST Therapy was found to reduce patients' pain in a study of 15 ulcers of vascular ischemia, sickle cell anaemia and venous stasis origin. One study found on average rection of 79% in subjective pain score in patients receiving u/s therapy. Another study reported decrease of almost 3 points on the subjective pain score following u/s treatment | Not indicated |

| Authors (year) | Aim/purpose of systematic review/outcomes | Interventions/ phenomena of interest | Databases sourced and searched | Types of studies included | Participant details | Number of studies included | Date range of database searching | Summary of results/findings | Context/setting/ geographical location of studies included |
|--|--|---|---|---------------------------|---------------------|----------------------------|----------------------------------|--|--|
| Smith D, Lane R, McGinnes R, O'Brien J, Johnston R, Bugaja L, Team V, Weller C ¹⁹ | To examine the effects of exercise in addition to standard compression therapy on VLU characteristics, including time to heal, size and recurrence, pain, quality of life, adverse events, and economic outcomes | Compression only or compression and care as usual versus: Various- nurse led self-management counselling program, including physical therapy and adherence to compression therapy Home based 12 week progressive resistance exercise program including compression Nine week exercise programme, intervention group included training bikes under nurse supervision | Ovid Medline, Ovid EMBASE, Ovid CINAHL, The Cochrane Library, PsycINFO, Web of Science, and PEDRO | RCTs | Adults with VLU | 6 studies | 1946 to 2018 | The visual analogue scale ranging between 0 and 10, whereby a score of 0 indicates no pain and a score of 10 indicates severe pain, was used to assess the participants' pain levels. Means and measures of variance were not reported nor provided upon request; thus, we could not analyse this outcome. One study reported Pain not associated with increasing the number of daily steps ($P = 0.45$) Relationship between pain and healing time not statistically significant ($P = .88$) Another study reported No association b/w pain and range of ankle mobility | Outpatient centres, home based or university hospital |

Appendix 6: Summary of characteristics of the hand search of systematic reviews for physical therapies

| Authors (year) | Aim/purpose of systematic review/outcomes | Interventions/phenomena of interest | Databases sourced and searched | Types of studies included | Participant details | Number of studies included | Date range of database searching | Summary of results/findings | Context/setting/geographical location of studies included |
|---|--|---|--|---|--|----------------------------|---|---|---|
| Purcell A, Buckley T, King J, Moyle W, Marshall A ⁵⁶ | Chronic leg ulcers are painful and if oral medication is not sufficient or compulsory, is there evidence for effectiveness of local treatment methods in pain treatment for wound-related pain | Topical analgesics were investigated in 10 studies, ibuprofen as intervention in 7 studies and morphine gel in 3 articles. Local anaesthetics were in 13 studies | MEDLINE, EMBASE, CINAHL, Joanna Briggs Institute, PubMed, Cochrane Library | 19 RCTs, 1 quasi-experimental study, 2 crossover studies and 1 retrospective observational medical record review. | 3783 | 23 | 1990 to 2019 | Lidocaine/prilocaine cream and ibuprofen foam significantly decreased wound-related pain during debridement and maybe promising in treating pain daily basis Morphine gel was ineffective according to this review | 20 studies in Europe, five in Sweden |
| Costa Ferreira SA, Serna Gonzalez CV, Thum M, Costa Faresin AA, Woo K, Gouveia Santos VLC ⁵⁶ | Malignant fungating wounds (MFW) are painful, this article was investigating if pain relief is possible by topical therapy and which topical therapies are being used | 20 different therapies as intervention were identified, wound dressings (58%), analgesic drugs (55.5%), topical antimicrobials (25.7%), skin barriers (15.7%), cryotherapy (5.7%), negative pressure wound therapy (4.3%) | CINAHL, LILACS, Embase, Web of Science, PubMed, Cochrane library, NICE, Scopus, JBSRR, grey literature | non-systematic reviews, 6 clinical trials | not assessed | 70 | No time limit, 22 studies were conducted 2015 to 2022 | This review categorized topical therapies used into groups of anti-adherent, antimicrobial, anti-inflammatory, absorbent dressing and analgesic drugs, negative pressure wound therapy, cryotherapy, and careful irrigation and removal of dressings 11 studies recommended the applying topical therapy to the periwound skin | England, Poland, US, Switzerland, Canada, Spain, Scotland, Australia, New Zealand, Brazil, China, Denmark, France |
| Upton D & Andrews A ³⁰ | This review investigated pain and skin trauma that may be experienced during negative pressure wound therapy (NPWT) | Pain levels measured during NPWT treatment and dressing changes, factors affecting pain during dressing change, and if different types of dressings/fillers or different NPWT systems (were affecting pain | CINAHL, MEDLINE, PsycINFO, Academic Search Complete, PsycARTICLES | Not categorized systematically; systematic review, RCTs, multicenter clinical study, several case studies | Not reported systematically. Mentioned number of participants in 19/30 articles (variety 1-208), total of 906 participants counted from these 19 articles. | 30 | 2001 to 2012 | Pain and trauma should be minimized during NPWT. Using atraumatic dressings/fillers may affect on pain during NPWT, but it remains unclear how different factors during NPWT cause pain and therefore it remains resolved how to treat properly NMWT-related pain | Not mentioned |

Appendix 7: Summary of evidence related to dressings for wound-related pain (supplementary Evidence from Companies)

| Author/s | Article title | Type of study | Results | Pain assessment tool/ score |
|---|--|---|---|--|
| Beitz AJ, Newman A, Kahn AR, Ruggles T, Elkmeier ³⁹ | A polymeric membrane dressing with antinociceptive properties: analysis with a rodent model of stab wound secondary hyperalgesia | Experimental study | Significant reduction in the development of both mechanical and thermal hyperalgesia. Analysis of spinal cord Fos expression demonstrated that the polymeric membrane dressing significantly decreased stab wound-induced Fos expression in laminae I to VI of the ipsilateral L3-L5 cord segments. Application of the polymeric membrane elicited Fos expression in laminae III and IV of the lumbar spinal cord. Demonstrated that the polymeric membrane dressing is capable of significantly reducing secondary hyperalgesia | C-Fos expression in the spinal laminae & activity |
| Klode J, Schöttler L, Stoffels I, Körber A, Schadendorf D, Dissemmond J ³⁷ | Investigation of adhesion of modern wound dressings: a comparative analysis of 56 different wound dressings | Experimental study - adhesion of wound dressings | The energy required to remove the wound dressings from human skin, was measured in Newton (N) and the following median values were obtained: hydrocolloid (2.25 N) > acrylate (1.14 N) > polyurethane (0.9 N) > silicone (0.7 N). The subjective pain intensity (VAS) with values ranging from 0 to 10. For hydrocolloid, it was 6.8, for acrylate 4.9, for polyurethane 3.1 and for silicone 2.5 points VAS. In comparison with human skin, the adhesion of wound dressings was significantly higher on steel (P < 0.0001), but was different for the different groups of wound dressings. Moreover, there was a statistically significant correlation between the adhesion and pain intensity (correlation coefficient 0.806; P = 0.01) | VAS 1-10 used to measure pain intensity |
| Davies SL & White RJ ¹⁴⁰ | Defining a holistic pain-relieving approach to wound care via a drug free polymeric membrane dressing | Literature review / theoretical review of how polymeric membrane dressings impact on the modulation of nociception in chronic wounds, wound-related pain and clinical outcomes. | Polymeric membrane dressings could impact on inflammation, its dissemination beyond a site of injury, nociceptor activation and the neuromodulation that is linked to tissue damage | Suggestion that polymeric membrane dressings could have a direct effect on pain associated with inflammation |
| Derbyshire A ³⁸ | Using a silicone-based dressing as a primary wound contact layer | Case studies (n=2) | Cases related to a burn injury and weeping eczema | Role of silicone dressings in reducing pain related to dressing change |
| Hegarty F & Wong M ¹¹⁴ | Polymeric membrane dressing for radiotherapy-induced skin reactions | An evaluation of the use of a polymeric membrane dressing (PolyMem®, Aspen Medical) in 23 patients with skin reactions following radiotherapy | A purpose-designed evaluation form was completed over a period of 4 weeks or until healed. Patients were asked to complete both qualitative descriptions and numerical scores of pain for symptoms and procedural pain. Skin healing, pain and sleep patterns were all evaluated, with additional qualitative input on the patient experience. Successful symptom management regarding pain, exudate control and patient comfort was documented in both clinical observations and patient diaries | Numerical scale Wong-Baker Faces Rating Scale (1988) |
| Tickle J ¹⁴³ | Positive clinical and patient outcomes with a next generation foam dressing | Two clinical evaluations of AQUACEL® Foam dressing 40 locations across the UK | 75 patients Majority with leg ulcers, pressure ulcers patient pain rating (using a VAS of 0 [no pain] to 10 [worst pain]) At the final dressing change, the majority of patients experienced no pain whilst the dressing was in situ (Figure 6a) or at dressing removal (Figure 6b) (83% and 84%, respectively) (five non-responders) | VAS |

| Author/s | Article title | Type of study | Results | Pain assessment tool/ score |
|--|--|--|--|--|
| Gefen A ¹⁴¹ | Managing inflammation by means of polymeric membrane dressings in pressure ulcer prevention | Literature Review/Discussion | Inflammation is the immediate normal response of the immune system to localised microscopic cell damage that precedes macroscopic tissue damage. Inflammation is triggered by secretion of chemokines that attract immune system cells to the sites of cell damage and facilitate their extravasation through increase in capillary permeability. The increased permeability of capillary walls in the inflammatory state consequently causes fluid leakage from the vasculature and, hence, oedema and associated pain. Polymeric membrane dressings (PolyMem®; Ferris Mfg, Corp.) are multifunctional dressings that focus and control the inflammation and oedema, and reduce pain. The literature reviewed in this article suggests that by having these effects on the inflammatory response, especially in fragile patients, the PolyMem dressing technology may facilitate repair of micro-damage in cell groups, which counteracts the evolution of damage to a macroscopic (tissue) level. Reducing the spread of inflammation and oedema in tissues appears to be a unique feature of PolyMem dressings, which supports repair of cell-scale damage under intact skin and tilts the delicate balance between the counteracting damage build-up and tissue repair mechanisms, thus promoting reversibility and self-healing | Extends the discussion of the role of polymeric membrane dressings in the control of inflammation, oedema and pain |
| King B and Barrett S ¹¹³ | A clinical evaluation of 20 patients when using a new absorbent silicone foam wound dressing: Cutimed Siltec B | Clinical/Product evaluation 20 wounds (3 dressing changes) | There was an overall improvement in pain scores with only one patient scoring above 2 (pain score 3) at week three, whereas 4 patients had scored above 2 at the previous dressing change. This would support the claim that the silicone adhesive was atraumatic to remove | Pain Assessment Tool used: VAS 0-10 |
| Seckam A ¹¹⁵ | A multicentre, observational evaluation of the product characteristics of two absorbent foam dressings | Clinical evaluations | Cutimed Siltec and Cutimed Siltec B There was a statistically significant improvement (chi=15.28, p=0.009) in patients' general pain levels and during the initial and final dressing changes There was a significant decrease in reported pain from the initial visit to the final visit (Figure 3). Patients often suffer psychosocial implications (Wounds International, 2012) because of the various wound elements mentioned previously, thus the results presented here highlight the importance of pain management during dressing changes. A decrease in wound pain during dressing changes may be linked to atraumatic removal. Further investigation into the decrease in general pain is required. | Descriptive categories: No pain Mild pain Moderate pain Severe pain Very severe pain |
| Seckam AM, Twardowska-Sauchka K, Heggenmann J, Süß-Burghart A, Augustin M ¹⁴⁴ | Clinical performance and quality of life impact of an absorbent bacteria-binding foam dressing | Prospective multicentre observational study (5 study sites) was to assess the clinical performance and safety of Cutimed® Siltec® Sorbact® absorbent bacteria-binding foam dressing in wound healing and its impact on patients' quality of life | Wounds International. Optimising wellbeing in people living with a wound. An expert working group review. (International consensus document), 2012. http://tinyurl.com/3n86zcn (accessed 18 June 2019) There was a statistically significant difference in the perception of wound pain over time (chi-square=25.60, P value <0.0001). At visit 5, more patients reported no pain (40% versus 31%) and a little pain (35% versus 26%). At visit 1, 31% of patients reported their pain was experienced as 'quite a lot' and 'very much'. In contrast, at visit 5, 6% of patients reported 'quite a lot' or 'very much' pain | 'my wound hurt': Not at all A little Moderately Quite a lot Very much |

Summary of evidence related to topical medications for wound-related pain

| | | | | |
|--|---|-------------|--|--|
| Pearson WA, Prentice DA, Sinclair DL, Lim LY, Carville KJ ¹⁴⁵ | A novel topical therapy for resistant and early peristomal pyoderma gangrenosum | Case series | Crushed oral prednisolone tablet mixed with Stomahesive Protective Powder (Convatec) was applied topically to seven patients with PPG and resulted in pain relief and wound healing in six of seven patients | Findings relate to individuals with PPG, however may have some relevance for PG in other anatomical locations. |
|--|---|-------------|--|--|

Appendix 8: Summary Table of Systematic Reviews for Patient Education and Wound-Related Pain

| Authors | Aim/purpose of systematic review/outcomes | Interventions/phenomena of interest | Databases sourced and searched | Types of studies included and/or method | Participant details | Number of studies included | Date range of database searching | Summary of results/findings | Context/setting/geographical location of studies included |
|--|--|--|--|--|--|---|----------------------------------|--|---|
| Van Hecke A, Gryphonck M, Defloor T ¹⁴⁷ | Reasons for non-adherence to prescribed compression therapy, leg exercises and leg elevation from patients' and nurses' perspectives Determinants of non-adherence to leg ulcer treatment | Reasons or determinants of non-adherence | Medline, CINAHL and the Cochrane database | Qualitative – Phenomenological, Ground Theory, Focus Group, Heideggerian Hermeneutics, Questionnaire, discourse analysis | Patients with leg ulcers based on venous insufficiency or a combination of venous and arterial insufficiency | 31 (n=65/13 patients, n=108 health/social care professionals) | 1995 to December 2007 | Pain, discomfort and lack of valid lifestyle advice by healthcare professionals (e.g., conflicting advice, no specific advice, impossibility of instructions) were identified as primary reasons for non-adherence from patient's perspective A pain management programme is recommended. Effective cooperation with general practitioners for analgesia might be paramount in helping the patient to adhere to compression and leg exercise instructions. While pain improved with compression therapy, during the first week's pain levels may increase (Briggs & Closs 2006, Morison et al.2007). Therefore, nurses should warn the patient and provide coping instructions as this might reduce distress (Johnson1973). Also, advice on taking regular analgesia when starting compression is important as this might influence whether patients will persevere | Canada, Denmark, Australia, UK |
| Liberato SMD, Souza AJG, Costa IKF, Torres GdV, Fortes AF, Lira ALBdC ¹⁴⁸ | Nursing interventions used for the management of pain in people with venous ulcer | Any nursing intervention for pain management as per the Nursing Interventions Classification | PubMed, Cumulative Index to Nursing and Allied Health Literature (CINAHL), ISI Web of Knowledge, SCOPUS, The Cochrane Library and Latin American Literature and Caribbean Health Sciences (LILACS) | RCT (n=4), double-blind crossover clinical trial, prospective case series, clinical trial (not randomised) | Leg ulcers, venous, chronic | 7 (Number of participants not stated) | Search undertaken in June 2013 | Consider the referral of the patient, the family, and the persons significant to support groups and other resources when appropriate Social interactions based on Leg Club model | |

| Authors | Aim/purpose of systematic review/outcomes | Interventions/ phenomena of interest | Databases sourced and searched | Types of studies included and/or method | Participant details | Number of studies included | Date range of database searching | Summary of results/findings | Context/setting/ geographical location of studies included |
|---|---|--|--|---|--|----------------------------|-----------------------------------|--|--|
| Weller CD, Buchbinder R, Johnston RV ¹⁴⁸ | To assess the benefits and harms of interventions designed to help people adhere to venous leg ulcer compression therapy, to improve healing and prevent recurrence after healing | Interventions that aim to help people with venous leg ulcers adhere to compression treatments compared with usual care, or no intervention, or another active intervention Outcomes were ulcer healing, ulcer recurrence, quality of life, pain, adherence to compression therapy and number of people with adverse events Education with video versus education in written format | The Cochrane Wounds Specialised Register; The Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library); Ovid MEDLINE; Ovid MEDLINE (In-Process & Other Citations); Ovid EMBASE and EBSCO CINAHL. We also searched trial registries, and reference lists of relevant publications for published and ongoing trials | RCTs | Venous ulcers Majority aged > 60 Male preponderance in 2 studies | 3 (n=371 participants) | June 2015 No date restrictions | Edwards et al (2009) study assessed pain using the RAND instrument and SF-36 at 12 weeks, at 24 weeks they used the Medical Outcomes Study pain measure – 100 point continuous scale 24-week data, and found there may be a small decrease in pain intensity in the participants attending the Leg Club compared with home visit care (MD -12.75 points on 100 point scale, 95% CI -24.79 to -0.71) | Miami Australia Netherlands |

| Authors | Aim/purpose of systematic review/outcomes | Interventions/ phenomena of interest | Databases sourced and searched | Types of studies included and/or method | Participant details | Number of studies included | Date range of database searching | Summary of results/findings | Context/setting/ geographical location of studies included |
|--|---|---|---|--|---|---|----------------------------------|---|---|
| Gethin G, Probst S, Styja J, Christiansen N, Price P. ¹⁴⁹ | Evidence on the use of person-centred care (PCC) in chronic wound care management | Chronic wounds or chronic wound prevention Person-centred intervention | PubMed, Embase, Cochrane Library, CINAHL, Web of Science and Scopus | Seven randomised controlled trials (RCTs) four pre-test-post-test design, Quasi-experimental studies Study within an RCT, Retrospective study Outcomes monitoring | Diabetic foot ulcers, venous leg ulcer, pressure ulcers | 17 studies (3149 patients, 36 Healthcare professionals) | 2009 to 2019 | Impact of Leg Club on pain reduction Kelechi et al. described in their comparative 8-week study, a nurse-directed and patient-centred educational programme among 21 patients. ⁶⁸ The educational intervention included a 6-week motivational enhancement programme and conditioning activity for leg function plus two additional visits in weeks 6-8 without active motivational enhancement. The control group completed conditioning activities along with a handout at baseline and weekly visits. The results showed an overall pain reduction on a 10-point scale of 0.5±2.0, versus 2.4±2.0 (p=0.046); a motivation difference of 3.8±3.1, versus 4.4±2.9, and a self-efficacy difference of 1.2±3.6, versus 0.6±6.0. Tulleners et al. studied the impact of a new transdisciplinary specialist service supplemented with telehealth consultations offered to 29 patients with VLU. After detailed diagnostics and causal treatment, all participants received a tailored dressing plan upon completion of their appointment, with directions on dressing type, application and exercises if appropriate. The average quality of life score based on a 0-1 scale with 1 representing the 'best health you can imagine', increased from 0.69 to 0.94. | Australia (n=5) USA (n=3) UK (n=2) Iran (n=2) N=1 Morocco Germany Brazil Switzerland China |

| Authors | Aim/purpose of systematic review/outcomes | Interventions/ phenomena of interest | Databases sourced and searched | Types of studies included and/or method | Participant details | Number of studies included | Date range of database searching | Summary of results/findings | Context/setting/ geographical location of studies included |
|--|--|---|---|--|--|-------------------------------|----------------------------------|--|--|
| Thomas DC, Chui PL, Yahya A, Yap JW ¹⁵⁰ | The effectiveness of structured patient education on their knowledge, participation, wound healing, and QoL. | Structured patient education efficacy on improving knowledge or participation or wound healing progress or quality of life among patient with a pressure injury were included. Any patient education-related interventions (e.g., structured or condition-specific interventions) were included in this review. | PubMed, MEDLINE, CINAHL, ProQuest, and Cochrane Library | Four RCTs One quasi-experimental and three interventional studies | Adult patients with PI stage I to stage IV or at risk of developing PI | 8 studies 466 participants | 2009 to 2021 | improved patient knowledge, participation, and QoL with structured patient education QoL measured in five studies, two reported that patient education significantly affected QoL. EQ-5D-5L includes pain/discomfort SF-36 includes measurement of pain | Ireland Australia France Sweden India South Korea US |

Appendix 9: Summary Table of Primary Research Identified from Systematic Reviews

| Reference | Design | Population (n) | Aim | Setting | Intervention/s | Outcome measures | Results | Conclusion |
|---|--|---|--|---|---|---|--|---|
| Arora M, Harvey LA, Glinsky JV, Chhabra HS, Hossain S, Arumugam N, et al. (See Thomas et al. ¹⁵⁰) | Multicentre, prospective, assessor-blinded, parallel randomised controlled trial | Spinal cord injury, with pressure ulcers N=120: n=60 in the intervention n=60 in the control | To determine the effectiveness of telephone-based management of pressure ulcers in people with spinal cord injury (SCI) in low- and middle-income countries | India Bangladesh | Weekly advice by telephone for 12 weeks about the management of their pressure ulcers from a trained healthcare professional vs no intervention | The size of the pressure ulcer and 13 secondary outcomes including pain as measured by the Utility score: EQ-5D-5L | The mean between-group difference for the size of the pressure ulcer at 12 weeks was 2.3 cm ² (95% confidence interval of 0.3 to 4.9; favouring the intervention group). Eight of the 13 secondary outcomes were statistically significant | There was a statistically significant difference in the mean utility score between the groups 0.1 (0.02 to 0.2; P=0.01) in favour of the intervention Of note, the results reflect a younger age group (35 vs 36) and were mainly male (n=106) |
| Carlson, M, Vigen CLP, Rubayi S, Blanche EI, Blanchard J, Atkins M, et al. (See Thomas et al. ¹⁵⁰) | RCT | Adults with SCI, with history of one or more MSPUs over the past 5 years. (N=232) n=166 intervention n=66 in control group | To test the efficacy of a lifestyle-based intervention designed to reduce incidence of medically serious pressure injuries in adults with SCI PUPP program, six modules | USA National Rehabilitation Centre, ethnically diverse, low income | The Pressure Ulcer Prevention Program, a 12-month lifestyle-based treatment administered by healthcare professionals, largely via in-home visits and phone contacts Module 5 of the program - Happiness and Personal Well-Being - examined managing pain | Blinded assessments of annualized MSPU incidence rates at 12 and 24 months, based on: skin checks, quarterly phone interviews with participants, and review of medical charts and billing records. Secondary outcomes included number of surgeries and various quality-of-life measures | Annualized MSPU rates did not differ significantly between study groups. At 12 months, rates were .56 for intervention recipients, .48 for randomized controls, and .65 for nonrandomized controls. At follow-up, rates were .44 and .39 respectively for randomized intervention and control participants | Evidence for intervention efficacy was inconclusive Intervention and control groups improved with no statistically significant difference in many measures, including pain Predominantly male population |
| Edwards H, Courtney M, Finlayson K, Lindsay E, Lewis C, Shuter P, Chang A (See Liberato et al. ¹⁴⁶) | RCT | Clients with chronic leg ulcer N=56 n=28 intervention n=28 control | To investigate the effectiveness of a new community nursing model of care for clients with chronic leg ulcers in terms of levels of pain and ulcer healing | Australia | Leg Club model of care | Healing rates, levels of pain, mood, sleep, functional ability | Unable to access full text | Decreased levels of pain were experienced by Leg Club patients, which may be directly associated with improved sleep, mood and normal working habits |

| Reference | Design | Population (n) | Aim | Setting | Intervention/s | Outcome measures | Results | Conclusion |
|---|--------|--|---|-----------------------|---|--|---|--|
| Edwards H, Courtney M, Finlayson K, Shuter P, Lindsay E (See Gethin et al. 149) | RCT | Venous leg ulcers N=67 Intervention n=34 standard care n=33 | To determine the effectiveness of a new community nursing model of care on quality of life, morale, depression, self-esteem, social support, healing, pain and functional ability of clients with chronic venous leg ulcers | Queensland, Australia | Lindsay Leg Club model (emphasising socialisation and peer support) vs traditional community nursing model (Home visits by a Registered Nurse) Participants in both groups were treated by a core team of nurses using identical research protocols based on short-stretch compression bandage treatment. Data were collected at baseline, 12 and 24 weeks from commencement | QoL, morale, depression, self-esteem, social support, healing, pain and functional ability Pain was measured using the Medical Outcomes Study (MOS) Pain Measures (Sherbourne 1992) | Participants who received care under the Leg Club model demonstrated significantly improved outcomes in quality of life ($p=0.014$), morale ($p<0.001$), self-esteem ($p=0.006$), healing ($p=0.004$), pain ($p=0.003$) and functional ability ($p=0.044$) Sequential analysis revealed that the intervention group mean scores had significantly greater decreases in the Severity of Pain subscale ($Z=3.02$, $p=0.001$), the Effect of Pain subscale ($Z=2.65$, $p=0.004$) and the overall total pain score ($Z=2.71$, $p=0.003$) when compared with the control | The Leg Club model of care shows potential to improve the health and well-being of clients who have chronic leg ulcers |

| Reference | Design | Population (n) | Aim | Setting | Intervention/s | Outcome measures | Results | Conclusion |
|--|--|--|--|---------|----------------|------------------|--|---|
| Green J, Jester R, McKinley R, Pooler A ¹⁵³ | Qualitative, unstructured interviews and non participant observation Phase 1 and 2 of a 4 Phase Study | Patients with leg ulcers 9 patients | Phase 1: to explore the lived experiences of patients Phase 2: to determine the extent to which the themes that were disclosed in phase 1 were explored by the nurse during a routine consultation. | UK | N/A | N/A | <p>Themes included; pain, issues relating to exudate and odour, social isolation and psychological effects</p> <p>Pain was reported by all nine participants and formed the very core of each interview. Pain dominated the patients' lives and limited their functioning. Across the participants, there were similarities in the description of their pain, including its unceasing nature, severity and timing; pain was reported to be especially problematic throughout the night. Many spoke of long nights, of being awakened by pain in the early hours of the morning and being unable to get comfortable and to go back to sleep again. All spoke of their reluctance to take analgesia, often because they were already taking a cocktail of medications for their comorbidities. Where analgesia was taken, respondents reflected that this was generally ineffective for the type and intensity of pain that their leg ulcers caused</p> <p>Phase 2: pain, a concern that had been readily raised during the interviews, was not explored on 42% of occasions and a solution was offered on only 23% of all occasions</p> | <p>The phase 1 and 2 study data demonstrate a mismatch between the impact of a concern for the patient and their likelihood of disclosure to their nurse, albeit for a small sample. The study highlights that nurses need to explore issues with patients during clinical consultations more effectively</p> |

| Reference | Design | Population (n) | Aim | Setting | Intervention/s | Outcome measures | Results | Conclusion |
|--|-------------------|--|---|---------|---|---|--|---|
| Kelechi TJ, Mueller M, Spencer C, Rinard B, Loftis G (see Gethin et al. 149) | Comparative study | Painful lower legs and critically colonised / infected wounds N=21 n=12 MECALF site A n=9 CALF site B | WOC nurse-directed, patient-centered intervention called MECALF (motivational enhancement and conditioning activity for leg function) compared to conditioning activities for lower leg function (CALF) alone | US | All patients received usual wound care per center protocol. The MECALF intervention was delivered by WOC nurses for 6 weeks at site A and a handout of CALF depicting the conditioning activities was provided by site staff (not WOC nurses) to patients at site B | Pre- and post-intervention outcome data were collected by study staff using pain, motivation, and self-efficacy scales, functional measures of physical activity, and physical measures of strength and range of motion | Patients reported that they were able to perform CALF. Overall pain was statistically significantly reduced (P=0.046) in both groups of patients with painful critically colonized/infected leg ulcers measured at week 8, two weeks after the study period. The CALF group experienced a slightly greater reduction in pain intensity than did the MECALF group. No statistically significant differences between the groups were observed in behavioural outcomes for motivation (P=0.641) and self-efficacy (P = .643), or for physical outcomes including overall ankle strength (P=0.609) and ankle range of motion (P=0.498). Functional and physical activity scores revealed no statistically significant differences in 3 measures, including Timed Up and Go test (P=0.624), Timed Chair Standing Test (P=0.686), or the Community Health Activities Model for Seniors (P=0.803) | No improvement in outcomes was observed with the addition of the WOC nurse-directed intervention. However, pain in the lower legs of patients with critically colonized/infected wounds in both groups improved after a 6-week behavioural physical activity intervention |

Appendix 10: Summary Table of Systematic Reviews for Psychological Aspects

| Authors | Aim/purpose of systematic review/outcomes | Interventions/ phenomena of interest | Databases sourced and searched | Types of studies included and/or method | Participant details | Number of studies included | Date range of database searching | Summary of results/findings | Context/setting/ geographical location of studies included |
|--|---|--|--|--|---|---|----------------------------------|--|---|
| Liberato SMD, Souza AUG, Costa IKF, Torres GdV, Fortes AF, Lira ALBdC ¹⁴⁶ | Nursing interventions used for the management of pain in people with venous ulcer | Any nursing intervention for pain management as per the Nursing Interventions Classification | PubMed, Cumulative Index to Nursing and Allied Health Literature (CINAHL), ISI Web of Knowledge, The SCOPUS, The Cochrane Library and Latin American Literature and Caribbean Health Sciences (LILACS) | RCT (n=4), double-blind crossover clinical trial, prospective case series, clinical trial (not randomised) | Leg ulcers, venous, chronic | 7 (No. of participants not stated) | Search undertaken in June 2013 | Consider the referral of the patient, the family, and the persons significant to support groups and other resources when appropriate Social Interactions based on Leg Club model | Canada, Denmark, Australia, UK |
| Gethin G, Probst S, Styja J, Christiansen N, Price P ¹⁴⁹ | Evidence on the use of person-centred care (PCC) in chronic wound care management | Chronic wounds or chronic wound prevention Person-centred intervention | PubMed, Embase, Cochrane Library, CINAHL, Web of Science and Scopus | Seven randomised controlled trials (RCTs) four pre-test post-test design Quasi-experimental studies Study within an RCT Retrospective study Outcomes monitoring | Diabetic foot ulcers, venous leg ulcer, pressure ulcers | 17 (3149 patients, 36 healthcare professionals) | 2009-2019 | Impact of Leg Club on pain reduction Kelechi et al. described in their comparative 8-week study, a nurse-directed and patient-centred educational programme among 21 patients. ⁶³ The educational intervention included a 6-week motivational enhancement programme and conditioning activity for leg function plus two additional visits in weeks 6-8 without active motivational enhancement. The control group completed conditioning activities along with a handout at baseline and weekly visits. The results showed an overall pain reduction on a 10-point scale of 0.5±2.0, versus 2.4±2.0 (p=0.046); a motivation difference of 3.8±3.1, versus 4.4±2.9; and a self-efficacy difference of 1.2±3.6, versus 0.6±6.0 Tulleners et al. studied the impact of a new transdisciplinary specialist service supplemented with telehealth consultations offered to 29 patients with VLU. After detailed diagnostics and causal treatment, all participants received a tailored dressing plan upon completion of their appointment, with directions on dressing type, application and exercises if appropriate. The average quality of life score based on a 0-1 scale with 1 representing the 'best health you can imagine', increased from 0.69 to 0.84. | Australia (n=5) USA (n=3) UK (n=2) Iran (n=2) n=1 in Morocco Germany Brazil Switzerland China |

Appendix 11: Summary Table of Evidence for complementary and alternative medicine

| Authors | Aim/purpose of systematic review/outcomes | Interventions/phenomena of interest | Databases sourced and searched | Types of studies included and / or method | Participant details | Number of studies included | Date range of database searching | Summary of results/findings | Context/setting/geographical location of studies included |
|--|---|-------------------------------------|--|---|--|----------------------------|--|---|---|
| Fox C. ¹⁸⁸ | To identify whether in adults with chronic wounds, the use of honey as a wound dressing improves wound management outcomes. | Honey | Cochrane Library Medline Cumulative Index to Nursing and Allied Health Literature Eribase Aned | Individual or multiple case studies | Recalcitrant surgical wound Chronic Wounds Ulceration Chronic infected wounds Leg Ulceration | 6 (n=66 patients) | (1966–present) (CINAHL, 1984–present) (1980–present) (1985–March 2002). | Five of the studies examined the effect of honey on pain. Three reported a decrease in pain. Case studies were of limited quality. No measure of pain assessment was discussed. | Not discussed |
| Mwipatayi BP, Angel D, Norrish J, Hamilton MJ, Scott A, Sleumarine K. ¹⁸⁹ | To investigate the clinical effects of topical honey on chronic leg ulcers Outcomes – healing time and antimicrobial effect Pain was discussed as part of the properties of honey background section but not evident in the review of studies | Topical Honey | PubMed, MEDLINE, EMBASE, CINAHL database and the Cochrane Library | Clinical Trials (not randomised) | Chronic Leg Ulcer (n=50) 3 groups: honey, phenytoin / honey and phenytoin. Honey-medicated dressing Chronic wounds (n=21), complicated surgical wounds (n=23), acute traumatic (n=16) | 2 | 1980 to 2004 | The studies analysed were influenced by different sources of bias, especially lack of blinding, poor reporting quality and poor sample size. None of those studies was an RCT. In order to elucidate the evidence for the use of honey as a first-line treatment in chronic leg ulcers, RCTs and laboratory studies on cellular effects are urgently needed | Africa Netherlands |

| Authors | Aim/purpose of systematic review/outcomes | Interventions/phenomena of interest | Databases sourced and searched | Types of studies included and / or method | Participant details | Number of studies included | Date range of database searching | Summary of results/findings | Context/setting/geographical location of studies included |
|---|---|-------------------------------------|--|---|--|---|--|--|---|
| Bardy J, Slevin NJ, Mais KL, Molassiotis A ¹⁶⁰ | To synthesise the evidence regarding honey's role in health care and to identify whether this evidence applies more specifically to cancer care | Honey | EMBASE, CINAHL, AMED, MEDLINE, COCHRANE and PUBMED | RCTs (n=20) | Wounds (n=19) burns (n=11) skin (n=3) cancer (n= 5) others (n=5) | 43 patients 2 examined pain in patients with leg ulcers Dunford and Hanano (2004) – multi-centre, non-randomised (n=40) Pain reduced from 1.6 ± 1.22 to 1.08 ± 1.54 p <0.001 Oluwatosin et al. (2000) n=38, non-randomised comparative. Pain at end of treatment p=0.21 NS | EMBASE 1974 to date; CINAHL 1982 to date; AMED 1985 to date; BNI 1994 to date and MEDLINE 1951 to date | Honey was found to be a suitable alternative for wound healing, burns and various skin conditions and to potentially have a role within cancer care In the cancer setting, honey may be used for radiation-induced mucositis, radiotherapy-induced skin reactions, hand and foot skin reactions in chemotherapy patients and for oral cavity and external surgical wounds | UK Nigeria 1 |

| Authors | Aim/purpose of systematic review/outcomes | Interventions/phenomena of interest | Databases sourced and searched | Types of studies included and / or method | Participant details | Number of studies included | Date range of database searching | Summary of results/findings | Context/setting/geographical location of studies included |
|---|---|---|--|--|--------------------------------------|---|-----------------------------------|---|---|
| Vandamme L, Heynenan A, Hoeksema H, Verbelen J, Monstrey S ¹⁶² | To evaluate the available evidence and the role of honey in contemporary wound care | Honey and wound healing: Antibacterial effect Healing stimulating properties Anti-inflammatory effect Odour reducing capacity Wound Pain | PubMed and ISI Web of Science | RCT (n=25) CCT (n=2) CT (n=5) CR (n=23) | Human burns, ulcers and other wounds | 55 studies 19 related to 'ulcers' including VLU, DFU, PUIPI, | Up to July 15, 2012 | Ulcers According to only one RCT, honey significantly reduces wound pain (Tables 4 and 5). The available evidence for these qualities is therefore weak. Overall, it can be concluded that the evidence for the antibacterial, anti-inflammatory, deodorising, debridement and wound pain-reducing properties of honey in ulcers is less conclusive. Most evidence had been found for the wound size-reducing effect of honey, which was statistically significant in favour of honey in 50% of the trials Other wounds Five RCTs report the parameter wound pain, but only two of them found a positive result in favour of honey; however not significant (Tables 4 and 5). Evidence for its deodorising, debridement, anti-inflammatory, and wound pain reducing properties is rather limited. | Not specified |
| Yaghoobi R, Kazerouni A, Kazerouni O ¹⁶³ | Antioxidant, antibacterial and anti-inflammatory properties of honey. | Honey | CINAHL, BioMed Central, Cochrane Library, Medline and Embase | RCTs Reviews | Animal Human | Not stated | Last 30 years up to December 2012 | Honey has antioxidant, antibacterial and anti-inflammatory properties. It can be used as a wound dressing to promote rapid and improved healing. These effects are due to honey's antibacterial action, secondary to its high acidity, osmotic effect, antioxidant, and hydrogen peroxide content. Using honey leads to improved wound healing in acute cases, pain relief in burn patients and decreased inflammatory response in such patients. However, it has proven to be ineffective in chronic leg ulcers Anti-inflammatory action: The anti-inflammatory action of honey reduces oedema and exudates, which can subsequently improve wound healing. This effect also reduces pain caused by pressure on nerve endings and reduces the amount of prostaglandin produced in the inflammatory process | Not reported |

| Authors | Aim/purpose of systematic review/outcomes | Interventions/phenomena of interest | Databases sourced and searched | Types of studies included and / or method | Participant details | Number of studies included | Date range of database searching | Summary of results/findings | Context/setting/geographical location of studies included |
|--|---|--|--|--|--|---------------------------------|----------------------------------|--|--|
| Oryan A, Alehzadeh E, Moshiri A ¹⁶⁴ | To review the mechanisms and therapeutic properties of honey on wound healing | Mechanisms and therapeutic properties of honey on wound healing | Not stated | Not stated | Not stated | Not stated | Not stated | In relation to the anti-inflammatory activity Reduced oedema and pain (6 studies) Debridement action contributes to the painless lifting off of the slough (3 studies) | |
| Vyhřeláková D, Kozáková R, Zeleníková R ¹⁶⁶ | To identify the effectiveness of products containing honey in the management of nonhealing wounds | Honey | PubMed, Science Direct, EBSCO and Google Scholar | 13 primary studies retrieved RCT, 8 studies Prospective, 5 studies | The number of participants in the assessed studies ranged from 10 to 375. Mostly, adults with diabetic and lower leg ulcers, or malignant fungating wounds (MFV) | 20 | 2007-2017 | Studies assessed in the review investigated the mean wound healing time, number (percentage) of completely or partly healed cases, pain intensity, odour and antibacterial activity of honey. The outcomes of most studies showed a shorter mean healing time, higher percentages of completely healed wounds and more effective eradication of wound infection. Only three studies reported no significant improvement in the treatment of lower leg and diabetic ulcers and malignant wounds with honey. CONCLUSION: Honey is an effective substance in the management of wounds and may be used at any phase of healing for any type of wounds, providing that the patient's allergies to some components of dressings are ruled out. | Belgium Egypt Germany Portugal Qatar New Zealand Malaysia Denmark Greece Saudi Arabia India Pakistan Hong Kong |
| Anastasiou IA, Eleftheradou I, Tentolouris A, Samakidou G, Papanas N, Tentolouris N ¹⁶⁵ | To summarise the therapeutic properties of honey and the data regarding its possible favourable effects on diabetic wound healing | Therapeutic effects of honey in vitro effect, and the efficacy and/or mechanism of action of several types of honey used for the treatment of diabetic animal wounds | MEDLINE, EMBASE, and the Cochrane Library | In vitro and in vivo | Animals | No PRISMA flow diagram included | 1986 to April 2021 | Evidence from 4 studies suggested that honey can reduce prostaglandin levels and thus decrease oedema, exudation and inflammation, and ultimately enhance wound healing and reduce topical pain Also, a suggestion that it provides painless debridement | |

| Authors | Aim/purpose of systematic review/outcomes | Interventions/phenomena of interest | Databases sourced and searched | Types of studies included and / or method | Participant details | Number of studies included | Date range of database searching | Summary of results/findings | Context/setting/geographical location of studies included |
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| Rojczyk E, Klama-Baryla A, Łabuś W, Wilemska-Kucharczewska K, Kucharczewski M ¹⁷⁰ | To provide an overview of information on Polish research on propolis and its medical application with particular emphasis on studies concerning wound healing. | Propolis | PubMed, Web of Science, Google Scholar | All Polish research that has contributed to the topic | Animals Humans | Undisclosed | Undisclosed | Use of propolis for pain associated with mouth ulcers (recurrent aphthous stomatitis) and post-tonsillectomy Anti-inflammatory activities discussed Propolis-based dressings and pain not discussed per se | Polish Research |
| Yilmaz AC & Aygin D ¹⁶⁷ | To evaluate the place of honey in wound treatment by investigating the randomised controlled studies | Difference of honey from other wound care materials in wound healing | MEDLINE, CINAHL, PUBMED, Google Scholar and Cochrane databases | RCTs | Human studies including burns, ulcers (Chronic Wounds), pressure sores, trauma, and post-operative wounds (n=17) Total number of patients – intervention and control 1716 | 30 | 2009 to 2019 | Honey in acute and chronic wounds provided rapid epithelialisation and wound contraction in wound healing, had anti-inflammatory and debridement effects, decreased the pain, ensured infection control, shortened the time of wound healing and was cost-effective Four studies mentioned pain as an outcome specifically. One study related to burn wounds. Three included chronic wounds (unspecified) | n=3 studies Pakistan Iran India n=2 studies Saudi Arabia n=1 study Denmark Indonesia Greece China Czech Republic UK |

| Authors | Aim/purpose of systematic review/ outcomes | Interventions/ phenomena of interest | Databases sourced and searched | Types of studies included and / or method | Participant details | Number of studies included | Date range of database searching | Summary of results/findings | Context/setting/ geographical location of studies included |
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| Aryanywu, GO, Nisar-ur-Rehman N, Onyeneke CE, Rauf K ⁷⁴ | To provide for the first time a repository of ethnopharmacological information while critically evaluating the relation between the traditional medicinal uses, chemical constituents and pharmacological activities of the Anthocleista species so as to unveil opportunities for future research. | Anthocleista species | PubMed, Google Scholar, Scifinder, Web of Science, Scopus, PubChem and other web sources | Unspecified Animal and human | Unspecified Where pain was mentioned this was for chest and abdominal pain Effect on pain also measured in animals: infliction of acute injuries | Unspecified | Unspecified | Anthocleista species showed antidiabetic, antiplasmodial, antimicrobial, hypotensive, spasmogenic, anti-obesity, antitumorogenic, analgesic, anti-inflammatory, antioxidant, antitypanosomal, anthelmintic, fertility, diuretic and laxative activities which supports most of their uses in traditional medicine. | For pain, wounds and inflammation studies: Nigeria Cameroun Guinea Cote d'Ivoire Kenya Tanzania Ghana Gabon Equatorial Guinea Congo |

| Authors | Aim/purpose of systematic review/outcomes | Interventions/phenomena of interest | Databases sourced and searched | Types of studies included and / or method | Participant details | Number of studies included | Date range of database searching | Summary of results/findings | Context/setting/geographical location of studies included |
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| Tschlakidou A, Govina O, Vasilopoulos G, Kavga A, Vastardi M, Kalemkerakis I ¹⁷¹ | Symptom management of malignant fungating wounds | Any intervention in the management of MFW Managing the main symptoms, which are malodour, exudate, pain and bleeding MA(S)D Manuka Honey NPWT Foam vs Silver Foam Bleeding | Medline | Cross-sectional (n=20) Case Study (n=1) Patient Group Study (n=5) Qualitative Descriptive & Cross Sectional (n=24) RCT (n=26) Case Study (n=1) Case Study (n=1) RCT (n=69) Single-blind RCT (n=67) Case study (n=1) Case study (n=2) | Breast Oral SOC Melanoma, Sarcoma (2), Breast Breast Breast, head, neck and other locations SOC SOC Breast, head, neck and other locations Breast, head, neck and other locations SOC Torso | 9 | 2008 to 2017 | According to the results, odour and exudates were significantly decreased by the use of honey and silver dressings. Wound cleaning with saline or tap water and the use of metronidazole had also positive results. Pain management was performed by the systematic use of opioids and the administration of an additional dose prior to the dressing change | |

| Authors | Aim/purpose of systematic review/outcomes | Interventions/phenomena of interest | Databases sourced and searched | Types of studies included and / or method | Participant details | Number of studies included | Date range of database searching | Summary of results/findings | Context/setting/geographical location of studies included |
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| Peplow PV, Chung T, Baxter GD ¹⁷⁷ | To provide evidence of the scientific bases by examining the effects in humans and animals of two clinical applications of low-level laser technologies | Effects in humans and common laboratory animals of laser acupuncture for pain relief and laser-stimulated wound healing | PubMed | 15 human clinical trials 16 animals (rat) Case studies Observational | 41 patients in total – not chronic wounds Modified VAS used for pain (self-evaluation) Or 'patients reporting of pain' – not specified | 31 Laser-stimulated wound healing N=5 human studies Pain and inflammation | End of January 2010 | Results consistently demonstrated the potential of laser irradiation to reduce pain and inflammation, improve blood flow, and stimulate wound repair The consensus from the included studies on laser acupuncture and laser-stimulated wound healing is positive in terms of supporting the rationale for the application of laser to decrease pain and inflammation, improve blood flow, and increase tissue regeneration | Not specified |
| Liberato SMD, Souza AJG, Costa IKF, Torres GdV, Fortes AF, Lira ALBdC ⁴⁶ | Nursing interventions used for the management of pain in people with venous ulcer | Any nursing intervention for pain management as per the Nursing Interventions Classification | PubMed, Cumulative Index to Nursing and Allied Health Literature (CINAHL), ISI Web of Knowledge, SCOPUS, The Cochrane Library and Latin American Literature and Caribbean Health Sciences (LLACS) | RCT (n=4), double-blind crossover clinical trial, prospective case series, clinical trial (not randomised) | Leg ulcers, venous, chronic | 7 studies (No. of participants not stated) | Search undertaken in June 2013 | Consider the referral of the patient, the family, and the persons significant to support groups and other resources when appropriate Teach the use of non pharmacological techniques before, after and, if possible, during painful activities; before the pain occurs or increase; and along with other measures of pain relief | Canada, Denmark, Australia, UK |

Traditional Chinese Medicine

| Authors | Aim/purpose of systematic review/outcomes | Interventions/phenomena of interest | Databases sourced and searched | Types of studies included and/or method | Participant details | Number of studies included | Date range of database searching | Summary of results/findings | Context /setting/ geographical location of studies included |
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| Ma X, Zheng C, Hu C, Rahman K, Qin L ¹⁷² | One section examined: Anti-inflammatory, antipyretic and analgesic activity Animal studies – not related to pain and wounds | Ethnopharmacological uses in Chinese medicine, phytochemistry, pharmacology and toxicology of <i>Desmodium</i> species | Chinese Herbal Classics PubMed, Scopus and Web of Science, SciFinder | Experimental Animal Human | Animals Humans | Unclear | Not reported | | Not reported |
| Li X, Xiao QQ, Ze K, Li S, Wang YF, Zhou M, Yang QT, Li FL, Li B ¹⁷³ | To evaluate the effectiveness of the external application of traditional Chinese medicine (EA-TCM) on venous ulcers. | The most common form of EA-TCM, used in nine trials, was ointment, including She, Xiang, Zhen, Zhu [20], Kui, Yang, Ping [9], Sheng, Ji [19], moist exposed burn [15], Sheng, Ji, Yu, Hong [11, 21], Hong, You [18, 22], and Fu, Fang, San, Huang ointments [23]. Other forms of EA-TCM used in clinical trials were powders in three trials [10, 14, 16], Chinese-herb external washing in three trials [17, 22, 24], paste in one trial [9], and oil in one trial [25] | MEDLINE, Excerpta Medica data BASE (EMBASE), Cochrane Central Register, China National Knowledge Infrastructure database, Chinese Scientific Journals Full Text Database, Wanfang Data Knowledge Service Platform, and the Chinese Biomedical Literature Service System | RCTs | Venous Ulcers A total of 1269 participants were included in these trials, with 660 and 609 in the experimental and control groups, respectively. The sample sizes of these trials ranged from 51 to 164 | 16 | Earliest citation to April 2015 | Sixteen of 193 potentially relevant trials met the inclusion criteria; however, their methodological qualities were low. Comparison of the same intervention strategies revealed significant differences in total effectiveness rates between EA-TCM and conventional therapy groups (RR = 1.22, 95% confidence interval [CI] = 1.16– 1.29, and $P < 0.00001$). Compared to conventional therapy, EA-TCM combined with conventional therapy had a superior total effectiveness rate (RR = 1.11, 95% CI = 1.04–1.19, and $P = 0.003$). There were no significant differences in recurrence rates during follow-up and final pain measurements between the experimental and those in the control groups (RR = 0.86, 95% CI = 0.31–2.39, and $P = 0.85$; MD –0.75, 95% CI = –2.15–0.65, and $P = 0.29$) The evidence that EA-TCM is an effective treatment for venous ulcers is encouraging, but not conclusive due to the low methodological quality of the RCTs. | China |

| Authors | Aim/purpose of systematic review/outcomes | Interventions/ phenomena of interest | Databases sourced and searched | Types of studies included and/or method | Participant details | Number of studies included | Date range of database searching | Summary of results/findings | Context /setting/ geographical location of studies included |
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| Ashraf K, Haque MR, Amir M, Ahmad N, Ahmad W, Sultan S, et al. (157) | Pharmacognosy, phytochemistry, phytochemical, and pharmacological properties of Ficus and its important species | Ficus deltoidea Jack (Moraceae) | Web of Science, Science Direct, Springer, Scifinder, PubMed, Scopus, Medline, Embase, and Google Scholar | Mainly experimental | Undisclosed – appears to be mainly animal studies | No PRISMA diagram included | Not disclosed | Suggested effects include: Anticancer Antibacterial Anti-inflammatory and antinociceptive Antitumorogenic (peptic ulcer) Wound Healing - suggestion that flavinoids protect tissue from oxidative stress Antioxidant Antidiabetic Uterotonic Little evidence to support the safety and efficacy | Not reported but appears to be Malaysia |

| Authors | Aim/purpose of systematic review/outcomes | Interventions/ phenomena of interest | Databases sourced and searched | Types of studies included and/or method | Participant details | Number of studies included | Date range of database searching | Summary of results/findings | Context /setting/ geographical location of studies included |
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| Ongarora BG ¹⁷⁵ | to explore the technological improvements in the management of chronic wounds | alleviating pain, promoting healing, or controlling wound infections. | PubMed, Scopus, Web of Science, Medline, and Clinical Trials | Articles in scientific journals | Not reported | 119 | Published after the year 2000 | <p>Low dosage of topical corticosteroid treatments is known to produce positive effects in chronic wounds. It accelerates healing, and reduces pain, besides suppressing hypergranulation tissue formation in 79% of the patients</p> <p>Ref- Hofman D, Moore K, Cooper R, Eagle M, Cooper S. Use of topical corticosteroids on chronic leg ulcers. J Wound Care. 2007; 16(5): 227-230.</p> <p>1 case study reporting on the use of ciprofloxacin (conventional drug) and Triphala (ayurvedic medicine)</p> <p>An ayurvedic procedure involving the washing of the affected part with Triphala (a formulation composed of Emblica officinalis, Terminalia chebula, and Terminalia bellirica) to reduce pain and infection was performed. The decoction was used daily together with the application of wound dressing with turmeric powder, neem bark powder, and Medhi honey. Gauze and a two-layered compression wrap were also applied. Ayurvedic protocols continued daily for a period of 6 weeks. Marma therapeutic strokes to the legs were performed by a practitioner once per week for 6 weeks to improve blood circulation and increased the reabsorption of pooled lymph fluid.</p> | Not reported |

Note: References mentioned in Appendix 11 refer to the reviewed articles.

WOUNDS

