

ORIGINAL ARTICLE

Background pain in persons with chronic leg ulcers: An exploratory study of symptom characteristics and management

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Abstract

This exploratory descriptive study aimed to describe characteristics and management of background pain related to chronic leg ulcers. A total of 121 participants were recruited from two wound care clinics using a consecutive sampling method. Data were obtained through screening interview, clinical examination, and questionnaires. The mean average background pain intensity was 4.5 (SD 2.56) (CI 95% 4.0-5.0). Pain interfered mostly with general activity (mean 4.3), sleep (mean 4.1), and walking ability (mean 4.0) (0-10 NRS). The most frequently reported descriptors of background pain were 'tender', 'stabbing', 'aching', and 'hot-burning'. Most of the participants stated that the pain was intermittent. Less than 60% had analgesics prescribed specifically for ulcer related pain, and the respondents reported that pain management provided a mean pain relief of 45.9% (SD 33.9, range 0-100). The findings indicate that ulcer related background pain is a significant problem that interferes with daily function, and that pain management in wound care is still inadequate.

KEYWORDS

chronic leg ulcers, holistic wound care, pain, pain characteristics, pain management

Key Messages

- a thorough pain assessment procedure is the cornerstone of successful pain management in persons with CLUs
- this cross-sectional explorative study aimed to describe characteristics and management of ulcer related pain in 121 persons with chronic leg ulcers
- ulcer related background pain is a significant problem, and the participants report moderate pain intensity, which interferes with general activity, sleep, and walking ability
- pain management seems to be inadequate, with less than 60% of the participants receiving analgesics for their ulcer related background pain

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1 | INTRODUCTION

Chronic leg ulcers (CLUs) are hard-to-heal wounds localised on the lower leg or foot, persisting for more than 6 weeks.¹ CLUs are common, and affect approximately 0.1% to 2% of the adult population in Western countries.² Ulcer related pain is a significant problem, and all CLUs are potentially painful.³⁻⁵ Pain is defined as 'an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage'.⁶ Ulcer related pain can be classified as background, incident, procedural, and operative.⁷ Background pain is caused by the underlying pathology of the leg ulceration and the wound itself, incidence pain stems from various daily activities, while procedural and operative pain is caused by wound treatment and debridement.⁸ From a clinical perspective, it is probably difficult for persons with CLUs to separate the experience of background pain from incidence pain.⁹ Hence, in this study, background pain is defined as ulcer related pain experienced in everyday life (other than procedural/operative pain).⁹ Ulcer related pain is often multi-causal in nature, and can be further classified as nociceptive, neuropathic, inflammatory, as well as acute and/or chronic.¹⁰⁻¹³ In addition, persons with CLUs are often old and may have multiple painful comorbidities.^{14,15} Consequently, persons with CLUs can have very complex pain conditions with the ulcer related background pain as an additional problem on top of living with a CLU and other painful comorbidities.

In the beginning of this century, several consensus statements based on expert opinion drew attention to the extent – and treatment of ulcer related pain.^{5,7,16} And the well-known concept of holistic wound bed preparation paradigm emphasises patient comfort and relieving pain in wound care.¹⁷ Effective pain management in wound care depends on detailed and accurate assessment and documentation of the pain experience, and a mix of psychosocial approaches together with local and systemic pain management should be implemented to control it.^{17,18} Most research studies on pain management in wound care have focused on the effects of different low-adherent or non-adherent dressings and topical analgesics and local anaesthetic agents mainly aimed to reduce dressing related pain.^{19,20} Larger studies assessing more extensive and holistic management are not available. However, despite the publication of clinical guidelines, consensus documents and research, ulcer related background pain is still not effectively assessed nor addressed in leg ulcer care,^{21,22} and background pain continues to be a frequent and substantial problem.²³

Most research studies on CLUs report on diagnosis, prevention, treatment, and healing rates.^{24,25} Few studies

report on ulcer related pain, and this research often concentrates on acute procedure-related pain and pain at dressing change. Knowledge is therefore scarce on the characteristics of ulcer related background pain. Intensity is the most commonly reported pain characteristic, and mean background pain intensity in CLUs is estimated at 3 to 4 (0-10 numeric rating scale).^{9,23,26} A limited number of studies describe other characteristics of ulcer related pain than intensity, such as pain descriptors, interference, and temporal pattern. Throbbing, tender, and burning were the most common descriptors of background pain.²⁶⁻²⁸ Sensory descriptors were typically used more often than affective descriptors.^{26,29} Ulcer related background pain can interfere with sleep,^{30,31} and one study found moderate pain interference in a sample with venous leg ulcers.³² Finally, background pain was worse during standing than at rest, and intermittent pain was more frequent than continuous pain.³³ Qualitative studies also support the use of sensory descriptors, varying intensity, and pain interference.³⁴ However, no previous studies provide a methodologically sound and comprehensive description of several characteristics of ulcer related background pain in a large sample of persons with CLUs.

CLUs are a substantial problem, and ulcer related background pain is a frequent and bothersome symptom disrupting quality of life. Knowledge about characteristics of ulcer related background pain is scarce and little is known about the pain management persons with CLUs receive. A thorough evaluation of the pain symptomatology in these persons is necessary for a better understanding of the pain experience and addressing the pervasive impact on function. Hence, the aim of the current study was to explore and describe characteristics of ulcer related background pain and pain management as reported by persons with CLUs.

2 | METHODS

2.1 | Design and participants

The current study is a descriptive analysis of cross-sectional data. The data collection was conducted from May 2017 to the end of December 2018. Consecutive sampling method was used to recruit participants attending two outpatient clinics for wound care in South-Eastern Norway. Inclusion criteria were: (a) presence of an open wound located below the knee; (b) wound duration of 6 weeks or longer; (c) age 18 years or older, (d) ability to understand and read Norwegian; and (e) no cognitive impairment causing comprehension difficulties. Exclusion criteria included the following ulcer diagnosis: burn-

ulcer, cancer-ulcer, radiation-ulcer, pressure ulcers caused by immobility, and immunological ulcers.

The present study sample was selected from a larger sample of persons with CLUs (reference deleted for blinded review). To explore pain characteristics, we analysed data from 121 persons who reported presence of ulcer related background pain in the screening interviews, and who returned the self-report questionnaires.

2.2 | Data collection

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.

2.2.1 | Screening interview

The initial brief interview was conducted by LL before the scheduled appointment at the wound care clinic. Participants were asked for the presence and type of ulcer related pain, and a structured questionnaire was used to gather data on wound duration and reoccurrence, as well as comorbidities.

2.2.2 | Clinical examination

During the scheduled appointment at the wound clinic, an examination was conducted by LL. Data were collected on ulcer characteristics, sensibility of the foot, location and temporal pattern of ulcer related pain, and pain management. Both participants self-report and patient records of pain management were incomplete in some cases. To ensure consistency of the clinical test, all tests were performed by one researcher LL.

Wound characteristics: The medical doctor assessed the ulcer and stated the ulcer diagnosis (ie, venous, diabetic, traumatic, unspecified). In addition, the researcher LL asked the participants about the presumed causal factor (eg, trauma, pressure), and identified and marked the localization of the ulcer on a body map of the lower leg. Wound size was estimated by multiplying the width and height (millimetres at the widest and highest) of the wound, calculating the area using the formula of an ellipse.

Sensibility of the lower leg: Tactile static mechanical sensation was assessed using Semmes-Weinstein monofilament (5.07/10 g) examination (SWME).³⁵ Two pricks with the monofilament were applied on each of four plantar sites on the forefoot (great toe, and base of first, third, and

fifth metatarsals). Inability to detect one prick is used as a diagnostic threshold when screening for diabetic peripheral neuropathy.³⁶ Vibration sense was assessed using a 128-Hz tuning fork. The vibrating tuning fork was first placed on bony prominence where neuropathy is unlikely (eg, hand). Once the participant was familiar with the vibration, the vibrating fork was applied to the bony prominence situated at the dorsum of the first toe just proximal to the nail bed.^{37,38} The respondents indicated whether they could feel the vibration with their eyes closed. Reduced or lost sense of vibration stimuli may indicate neuropathy.³⁹

Location of pain: Participants were asked to identify the pain location, such as directly in the wound bed; in the wound edges; in the area surrounding the wound; in the entire foot; in the entire leg, or a self-determined location. If more than one location was selected, 'multiple locations' were used to describe the location of the pain.

Temporal pattern of pain: To assess how pain fluctuated during the day, a question from the pain quality assessment scale (PQAS)⁴⁰ was used. PQAS is a valid tool for assessing various types of nociceptive and neuropathic pain,^{40,41} and is linguistically validated and culturally adapted in Norwegian.⁴² The participants were asked whether their pain was intermittent (feel pain sometimes, pain free at other times), variable (pain all the time, but also moments of more severe/different pain), or stable (constant pain that does not change).

Pain management: Participants were asked about their use of analgesics, and compliance to prescribed analgesics. Supplemental/confirmatory information was gathered from the patients' records when available. It was differentiated whether the pain management was aimed at ulcer related or other types of pain. Finally, participants were asked to describe other non-medical interventions used to relieve ulcer related pain.

2.2.3 | Questionnaires

All participants received a battery of self-report questionnaires on the day of recruitment and scheduled appointment at the wound clinic. The questionnaires were completed the following day and returned by mail in a pre-paid envelope. The questionnaires contained questions regarding demography and pain characteristics. Participants were specifically asked to keep in mind their ulcer related pain when answering questions regarding pain.

Demography: Information was obtained on age, gender, work situation, education, living arrangements, and ethnicity.

Short-form McGill pain questionnaire (SF-MPQ) was used to assess qualities of present ulcer related background pain. The SF-MPQ contains 15 pain descriptors (11 sensory,

four affective) with a four-point intensity scale for each word (ie, none, mild, moderate, severe). In addition, the SF-MPQ contains a present pain intensity index and a 0 to 100 mm visual analogue scale (VAS) to assess present pain intensity.⁴³ The Norwegian version of SF-MPQ has demonstrated reliability and validity in a Norwegian sample with musculoskeletal pain.^{44,45} The English version of SF-MPQ has been used to assess ulcer related pain.⁴⁶ The SF-MPQ was linguistically adjusted to specifically assess ulcer related pain by adding 'ulcer related' to the word 'pain' throughout the questionnaire. The Cronbach's alpha for all the descriptors were 0.87, and the Cronbach's alpha for the sensory and affective descriptors were 0.84 and 0.68, respectively.

The brief pain inventory (BPI) was used to provide information about the location, intensity, treatment, and interference of ulcer related pain on function in the last 24 hours. BPI consists of four 0 (no pain) to 10 (worst pain imaginable) numeric rating scales (NRS) on the intensity of pain in general, at its worst, at its least, and right now. A percentage scale (0-100) quantifies pain relief from current therapies, and a bodymap is provided to mark the pain location. Furthermore, seven questions address whether pain interferes with physical and psychosocial function.⁴⁷ The activity cluster of interference items (WAW) includes general activity, walking ability, work, and sleep, while the affect cluster of interference items (REM) includes mood, enjoyment of life, and relations with others. The translated Norwegian version of the BPI was validated for use in patients with cancer and osteoarthritis, demonstrating good validity and reliability.⁴⁸⁻⁵¹ The English version of the BPI was used to assess ulcer related pain.⁵² The BPI was linguistically adjusted to specifically assess ulcer related pain by adding 'ulcer related' to the word 'pain' throughout the questionnaire. Cronbach's alpha for both the activity cluster and the affect cluster of interference items were 0.89, and the Cronbach's alpha for all interference items was 0.93 in this study.

Avoidance of physical activities: The participants were asked if they avoided certain activities because of ulcer related pain using a yes/no format. If yes, the participants were asked to describe the activities in own words.

2.3 | Research ethics

Approval for the study was granted by the Norwegian Regional Ethical Comity for Medical and Health Research Ethics, region South-East (REK number 2016/1236). In addition, the Norwegian Center for Research Data (NSD), as well as the research manager and the head of department at the local hospitals, approved the study. Participants were informed both orally and written about the aims and procedures of this study, and written consent was obtained from all participants. They were

informed that the information they provided would be deidentified, and they could withdraw from the study at any time before the publication of the study.

2.4 | Data analysis

SPSS version 26 was used to perform descriptive statistical analyses. Categorical data are presented as frequencies with proportions, and continuous data are presented as means with standard deviation (SD) or medians with range. Chronbach's alpha was calculated for assessing the reliability of the BPI interference sub-scales and the NSF-MPQ total, affective, and sensory descriptors.

BPI and MPQ-SF were both scored according to the developers' recommendations.^{43,53} In the analysis, the BPI item number three (worst pain intensity) was transformed to an ordinal variable where 0 to 3.99 correspond to no/mild pain, ≥ 4 to 6.99 correspond to moderate pain, and ≥ 7 to 10 correspond to severe pain. These cut-off points are in line with previous studies.^{23,54,55}

Responses to open-ended questions were quantified into categories. Categories for avoidance of physical activity were walking, household chores, social activities, bending/crouching, and sitting with legs down. Categories for non-medical interventions were elevating the feet, activity, reduced activity, lowering feet, and other (ie, massage, ulcer care, aids to protect the ulcer).

There were few missing values on single items overall in the dataset. However, one single item, the SF-MPQ VAS present pain intensity item, had 27.3% missing values. Missing items on the 15 pain descriptors of SF-MPQ were replaced by 0. By experience, participants skip marking the pain descriptors that are not relevant to them, causing an inaccurate and high number of missing items.

3 | RESULTS

3.1 | Sample characteristics

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 (ie, on sick leave, retired) (Table 1).

3.2 | Clinical characteristics

The participants had at least one active ulcer located at the leg, ankle, or foot. Unspecified ulcer in lower extremities (ICD-10 diagnosis code L97) was the most frequent

diagnosis (30.6%). Most ulcers (48%) were triggered by a trauma, but most ulcers were further diagnosed based on physiological factors such as underlying diseases and vascular conditions. The mean wound size was 4.2 cm² (SD 8.8), and mean wound duration was of 28.5 weeks (SD 47.8) (Table 2).

For 46%, the present ulcer was not the first CLU they suffered from. A total of 94% reported at least one comorbidity. The most frequent comorbidities were coronary diseases (74%) including hypertension and arteriosclerosis, other painful conditions (52%) such as musculoskeletal pain, and diabetes (31%). Loss of tactile and vibration sensation was common: 59% obtained >8 on the SWME, and 51% did not detect vibration from the tuning fork (Table 2).

TABLE 1 Demographic data (N = 121)

| | N (%) |
|----------------------------|------------|
| Age | |
| <49 | 5 (4.1) |
| 50-59 | 11 (9.1) |
| 60-69 | 17 (14.0) |
| 70-79 | 44 (36.4) |
| 80-89 | 34 (28.1) |
| >90 | 10 (8.3) |
| Gender | |
| Male | 56 (46.3) |
| Female | 65 (53.7) |
| Marital status | |
| Single | 19 (15.7) |
| Married/cohabitant | 72 (59.5) |
| Widowed | 30 (24.8) |
| Educational level | |
| Primary school | 48 (39.7) |
| Secondary school | 37 (30.6) |
| University <4 years | 24 (19.8) |
| University >4 years | 9 (7.4) |
| Work situation | |
| Working | 13 (10.8) |
| Retired/sick leave | 106 (87.5) |
| Living arrangements | |
| Alone | 48 (39.7) |
| With spouse/other family | 73 (60.3) |
| Ethnicity | |
| Norwegian | 118 (97.5) |
| Other | 2 (1.7) |

Note: N, number of participants.

3.3 | Types of pain

In this sample, all participants reported having ulcer related background pain. One in five reported having only ulcer related background pain, while four in five reported both background pain and pain at dressing change (procedural) (Figure 1).

3.4 | Characteristics of ulcer related background pain

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) (Table 3). Divided into categories, 37% reported no or mild pain (NRS 0-3), 28% moderate pain (NRS 4-6), and 35% severe pain (NRS 7-10) (Figure 2).

Ulcer pain interference: 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).

Avoidance of physical activities: As many as 37% of the sample reported that they avoided certain activities (eg, walking, household chores, social activities, bending/crouching, sitting with legs down) to escape ulcer related pain.

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%).

Ulcer pain location: Most respondents (51.7%) stated that the ulcer related pain was located in multiple locations, and few (22.3%) reported that the pain was only located in the ulcer itself. The most frequent pain locations were the ulcer itself (74.4%), the surrounding area of the wound (55.4%) and the entire leg (10.7%).

Time pattern of ulcer pain: The majority stated that the ulcer related pain was intermittent (71.1%). None reported that the pain was stable.

3.5 | Ulcer pain management

A total of 76.9% confirmed they had analgesics prescribed. Of those, 58.7% had analgesics for ulcer related pain (Table 4). Analgesics were not used as prescribed by 25.8% of those with prescribed analgesics. The main

TABLE 2 Clinical characteristics (N = 121)

| | Median (IQR) | N (%) |
|--|-----------------|-----------|
| Wound diagnosis (as specified by doctor) | | |
| Unspecified (L97) | | 37 (30.6) |
| Venous | | 25 (20.7) |
| Diabetic foot ulcer | | 20 (16.5) |
| Traumatic | | 17 (14.0) |
| Arterial | | 9 (7.4) |
| Other | | 13 (10.8) |
| Wound size (cm ²) | 1.2 (0.46-4.32) | |
| Wound duration (weeks) | 15 (8-26) | |
| Reoccurring wound | | |
| Yes | | 55 (45.5) |
| No | | 57 (47.1) |
| Number of wounds | | |
| 1 | | 62 (51.2) |
| 2-5 | | 38 (31.4) |
| >5 | | 12 (9.9) |
| Presumed primary causal factor | | |
| Trauma | | 123 (48) |
| Pressure/friction | | 50 (19.8) |
| Venous insufficiency | | 16 (6.3) |
| Arterial insufficiency | | 5 (2) |
| Unknown/other | | 58 (23) |
| Wound location | | |
| Leg | | 44 (36.4) |
| Foot | | 36 (29.8) |
| Ankle | | 23 (19.0) |
| Multiple locations | | 18 (14.9) |
| Number of comorbidities | | |
| No of comorbidities | | 6 (5.0) |
| One comorbidity | | 24 (19.8) |
| Two comorbidities | | 35 (28.9) |
| Three comorbidities | | 30 (24.8) |
| Four or more comorbidities | | 26 (21.5) |
| Comorbidities | | |
| Coronary disease | | 90 (74.4) |
| Other painful conditions ^a | | 63 (52.1) |
| Diabetes | | 37 (30.6) |
| Malnutrition | | 25 (20.7) |
| Arthritis | | 22 (18.2) |
| Renal disease | | 20 (16.5) |
| Cancer (previous or present) | | 20 (16.5) |

TABLE 2 (Continued)

| | Median (IQR) | N (%) |
|------------------|--------------|-----------|
| Stroke | | 12 (9.9) |
| Asthma/COPD | | 8 (6.6) |
| SWME | | |
| 0-3/8 | | 42 (34.7) |
| 4-7/8 | | 29 (23.9) |
| 8/8 | | 42 (34.7) |
| Tuning fork test | | |
| Positive | | 62 (51.2) |
| Negative | | 49 (40.5) |

Abbreviations: IQR, interquartile range; SD, standard deviation; SWME, Semmes-Weinstein monofilament examination.

^aSuch as musculoskeletal pain and neuropathies.

compliance issue was not using the analgesic at all (n = 10) or using less analgesics than prescribed (n = 13). The reasons for not using/using less analgesics were several: adverse effects (drowsiness, constipation) (n = 8), fear of adverse effects (n = 6), no effect (n = 3), and no need for analgesics (n = 2), or a combination of these.

As many as 61.2% reported using non-medical interventions to show ulcer related pain, and most frequently they elevated the feet (23.1%) (Table 4). The respondents reported that the pain treatments or medications provided a mean pain relief of 45.9% (SD 33.9, range 0-100).

4 | DISCUSSION

This is one of the first research studies to provide solid knowledge of the characteristics of ulcer related background pain in persons with CLU's. While most other studies report on one or a few characteristics, this study describes the variety of pain characteristics of relevance for a holistic pain assessment and thereby effective pain management.

In the present study, the participants reported on average moderate ulcer related background pain (mean 4.5, CI 95% 4.0-5.0). This finding is supported our previous systematic review of pain in chronic venous ulcers (reference blinded for review), where we found an overall pooled estimate of mean pain intensity of 4.0 (CI 95% 3.5, 4.5). Interestingly, the SF-MPQ present pain intensity 0 to 100 VAS had almost 30% missing answers, which supports previous reports that VAS may

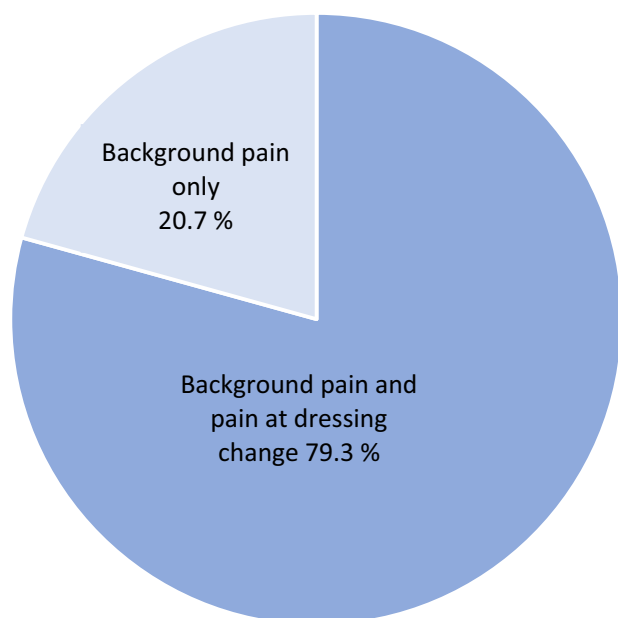


FIGURE 1 Background pain and pain at dressing change

not be an appropriate measure for pain intensity in the elderly.⁵⁶ Sub-analyses of the worst pain intensity scores in the present study demonstrated that 61% of the respondents reported moderate or severe pain intensity indicating a need for better pain management. Pain intensity worse than mild should be unacceptable.⁵⁷ The fact that as many as 34% of the respondents reported severe background pain intensity highlights the importance of looking further into existing pain management practice in wound care.

This study further demonstrates that ulcer related background pain interfered with daily function. In particular, activity functions (WOW) such as general activity, sleep, and walking ability were affected to a moderate degree.⁵⁸ In addition, 37% of the participants reported that they avoided certain activities, such as walking and daily chores. To a lesser extent, ulcer related pain interfered with affective functions such as enjoyment of life and mood (REM). However, enjoyment of life was moderately interfered with by ulcer pain. These findings are supported by previous research showing that chronic pain is associated with reduced physical activity^{59,60} and can lead to emotional and behavioural reactions.⁶¹ Note that pain interference does not necessarily provide an acceptable surrogate for physical and psychosocial function, and participants may have impaired function because of other factors than pain.⁶² In fact, in the present study, more than half of the participants had other painful comorbidities such as musculoskeletal pain, joint pain, and neuropathies. Previous research also shows that the ulcer itself,⁶³ older age,⁶⁴ and comorbidities⁶⁵ are

associated with impaired function and health outcomes. Recognising that ulcer related pain in addition to other factors can interfere with several aspects of a person's life are reasons to use biopsychosocial approaches in wound management. Biopsychosocial approaches might offset important negative consequences of a developing chronic pain problem. It is therefore essential to consider both the activity and affective dimension of pain interference as it allows assessing which aspects of the individuals' life (activity or affectivity) are affected by pain, and provide interventions accordingly.⁶⁶ Furthermore, it allows estimating the contribution of interventions in each of these aspects. Since physical activity is essential for wound healing,^{67,68} pain management for promoting physical activity should be an integrated part of holistic wound care.

The most frequent descriptors used to describe ulcer related background pain were 'tender', 'stabbing', 'aching', and 'hot-burning', which are all sensory descriptors. Tender and aching are traditionally associated with nociceptive pain caused by inflammation and tissue damage, while hot-burning and stabbing are often associated with neuropathic pain caused by injury and sensitization of the peripheral or central nervous system.⁶⁹ Several pathophysiological mechanisms of CLUs, such as tissue damage, inflammation, and nerve damage, may contribute to the manifestations and different types (eg, nociceptive, neuropathic) of ulcer related background pain.¹³ The fact that the participants reported different types of pain descriptors may indicate the presence of different types of pain. Note, however, that no descriptor is particular for either nociceptive or neuropathic pain, and therefore type of pain cannot be determined by pain descriptors alone. The use of descriptors in combination with a thorough history taking and clinical examination can guide clinicians in determining type of pain and choosing appropriate pain management.^{69,70}

The fact that nine participants reported 'no pain' in the last 24 hours is in concordance with the finding that most participants (71.1%) stated that their pain was intermittent, meaning that they experience pain sometimes, but are pain free at other times. Further, this finding indicates that at least some of the participants have pain free periods that exceed 24 hours. The remaining sample reported that their pain was variable, meaning that they had 'background' pain all the time, but also periods of less as well as more pain (eg, incident pain, pain attacks). Note that none of the participants described their pain as stable. The temporal fluctuation is important to recognise when assessing and treating ulcer related pain, in order to provide appropriate pain management. Persons with long pain free periods do not need continuous analgesia

TABLE 3 Ulcer pain characteristics (N = 121)

| | N (%) | Mean | SD |
|---|-----------|-------|-------|
| BPI pain intensity (0-10 NRS, past 24 hours) | | | |
| Worst | | 4.9 | 2.88 |
| Average | | 4.5 | 3.56 |
| Now | | 3.0 | 3.64 |
| Least | | 2.1 | 2.04 |
| BPI pain interference (0-10 NRS, past 24 hours) | | | |
| General activity | | 4.3 | 3.16 |
| Sleep | | 4.1 | 3.18 |
| Walking ability | | 4.0 | 3.11 |
| Normal work | | 3.9 | 3.14 |
| Enjoyment of life | | 3.6 | 3.09 |
| Mood | | 3.3 | 2.96 |
| Relations with others | | 2.4 | 2.69 |
| Activity pain interference (WAW) | | 4.1 | 2.8 |
| Affective pain interference (REM) | | 3.1 | 2.7 |
| Total interference score | | 3.6 | 2.6 |
| SF-MPQ | | | |
| Descriptors | | | |
| SF-MPQ sensory | | 6.90 | 6.66 |
| SF-MPQ affective | | 1.36 | 2.19 |
| SF-MPQ total | | 8.24 | 8.35 |
| VAS present pain intensity (0-100) | | 38.65 | 27.23 |
| Present pain intensity index | | | |
| No pain | 10 (8.3) | | |
| Mild pain | 22 (18.2) | | |
| Discomforting | 28 (23.1) | | |
| Distressing | 45 (37.2) | | |
| Horrible | 7 (5.8) | | |
| Excruciating | 2 (1.7) | | |
| PQAS pain pattern | | | |
| Intermittent pain | 86 (71.1) | | |
| Variable pain | 31 (25.6) | | |
| Stable pain | 0 (0) | | |
| Localization of ulcer related pain | | | |
| Multiple locations | 69 (57.0) | | |
| Only the wound itself (wound bed or edges) | 27 (22.3) | | |
| The wound bed | 90 (74.4) | | |
| The wound edges | 15 (12.4) | | |
| The area surrounding the wound | 67 (55.4) | | |
| The entire foot | 7 (6.0) | | |
| The entire leg | 13 (10.7) | | |

Abbreviations: BPI, brief pain inventory; NRS, numeric rating scale; PQAS, pain quality assessment scale; REM, affective pain interference; SD, standard derivation; SF-MPQ, Short-form Mc Gill pain questionnaire; WAW, activity pain interference.

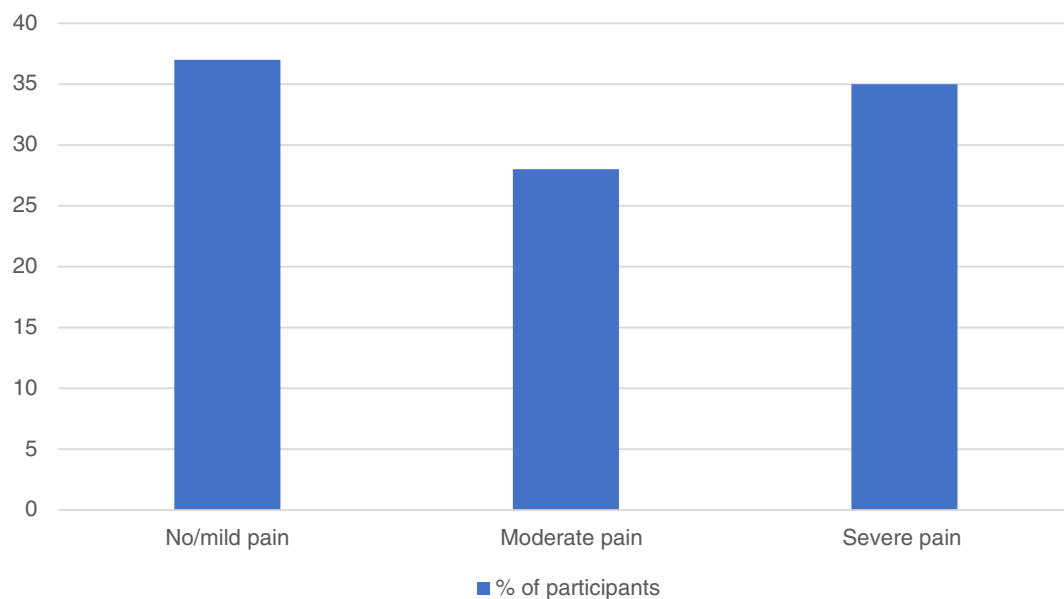


FIGURE 2 Brief pain inventory worst ulcer pain intensity divided into categories (N = 117)

TABLE 4 Ulcer pain management

| | n (%) |
|--|-----------|
| Prescribed analgesics | |
| Yes | 93 (76.9) |
| No | 28 (23.1) |
| Prescribed analgesics for ulcer related pain | |
| Yes | 71 (58.7) |
| No | 50 (41.3) |
| Use of non-medical interventions | |
| Yes | 74 (61.2) |
| No | 47 (38.8) |
| Type of non-medical interventions | |
| Elevating feet | 28 (23.1) |
| Activity | 16 (13.2) |
| Reduced activity | 13 (10.7) |
| Lowering feet | 9 (7.4) |
| Other ^a | 8 (6.6) |

^aMassage, ulcer care, aids to protect the ulcer.

administered around the clock (ATC), but rather administration per needed (PRN).⁷¹ Likewise, persons with variable pain may need ATC in addition to PRN to achieve pain relief. The temporal fluctuations of pain and pain intensity are especially important when taking into consideration that almost three out of four of the respondents reported both ulcer related background pain and dressing related pain.

A majority of the participants reported that their ulcer related pain had multiple locations. The present study does not provide further information about differences in pain characteristics based on the location. However, pain in other locations than the ulcer itself might be primary hyperalgesia because of inflammation,⁷² referred pain from the ulcer,⁷³ or caused by other pathological factors associated with having a CLU (eg, ischaemia, oedema, swelling, skin irritation, diabetic neuropathy). Interestingly, less than one out of four participants reported that the pain was located only in the ulcer itself. This finding indicates that local pain-relieving measures applied in the wound bed (eg, analgesic gels, analgesic-releasing dressings) are most likely inadequate to relieve pain. The location of pain should therefore be thoroughly examined when assessing ulcer related pain, as it could inform clinicians of the best combination of systemic and local pain management.

An interesting finding from the present study pertains to the assessment of tactile mechanical sensation. Only 30% of the respondents were diagnosed with diabetes, and only 16% had a diabetic foot ulcer. Yet almost 60% of the participants had reduced sensation and were unable to detect one or more pricks using SWME. Note that inability to detect one prick is used as a diagnostic threshold when screening for diabetic peripheral neuropathy.³⁶ In addition, over 40% could not detect vibration from the tuning fork. These findings demonstrate that many persons with other ulcer-diagnoses than diabetic ulcers (eg, traumatic, venous, and mixed aetiology ulcers) also had diminished tactile sensation in the lower leg.

Interestingly, studies have showed an alteration of nerve function in persons with both arterial- and venous ulcers,⁷⁴⁻⁷⁶ and vascular microangiopathy that lead to nerve ischaemia may result in neuropathy in persons with CLUs.⁷⁷ Note that lost sense of touch and vibration may indicate presence of peripheral neuropathy.³⁹ However, it is also well documented that diminished tactile sensation is common in healthy older adults.⁷⁸ Our present study cannot state whether the findings of diminished tactile sensation in persons with CLUs is a sign of peripheral neuropathy because of disease, or a normal alteration in the peripheral nervous system with increasing age. However, previous research also shows that ulcer related pain is prevalent despite diminished tactile sensation.⁷⁹ Therefore, the present study's findings are relevant in clinical practice, and should be a reminder for clinicians not to discard ulcer related pain in persons with CLUs and signs of non-painful peripheral neuropathy. The high prevalence of diminished tactile sensation is also important to consider with regards to treatment and prevention of CLUs, regardless of ulcer diagnosis. SWME and tuning fork tests are non-invasive, low-cost, rapid, and easy-to-apply in clinical practice. And even though there are several uncertainties in the diagnostics properties of the tests, the monofilament and tuning fork are important evidence-based tools for predicting the prognosis of persons with CLUs.^{36,38,80}

Interestingly, while a large proportion of the participants (77%) had prescribed analgesics, less than 60% had prescribed analgesics specifically for ulcer related pain. One out of four reported using doses less than prescribed or not taking the analgesic at all for several reasons. The fact that participants had intermittent pain and some pain-free periods of more than 24 hours may explain some of the non-adherence to prescribed analgesics. However, this study's findings of a large proportion of persons with moderate to severe pain with substantial impact on function may also indicate that the clinicians did not succeed in providing proper pain management. Previous research supports this study's findings that persons with CLUs experience different pain severity and relief, and they have different impact of pain on activity, sleep and negative emotions. In addition, they may experience different adverse effects of analgesics (eg, nausea, drowsiness).⁸¹ They may also have the same barriers to pain management as other patients, such as being afraid of addiction or believing that analgesics should only be used when pain is unbearable.^{82,83} All these factors may in turn affect adherence to treatment. Good quality pain management must involve assessment and evaluation of the response to treatment and be individualised to meet a person's various needs.

The present study has strengths and limitations that need to be recognised. First of all, this study is the first

of its kind to investigate a number of pain characteristics in depth in a large sample of persons with CLUs. The findings are relevant for persons with CLUs with various diagnoses, making the study clinically relevant for clinicians managing a variety of CLUs. However, since we only recruited hospital outpatients, our sample may not be representative of a community sample of persons with ulcer related pain caused by CLUs. Furthermore, we recruited persons with various ulcer diagnosis and therefore one should be careful when generalising the results to one specific wound patient group. However, the sample should be representative for persons with ulcer related background pain attending outpatient wound clinics.

This study provides detailed and systematic quantitative data concerning ulcer related background pain experienced by persons living with CLUs. The data support previous research that suggests that 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. Unfortunately, despite heightened awareness of and clinical advantages in pain management over the past 15 years, our study suggests that background pain is still undertreated in person with CLUs. Considering the other pain characteristics presented, we further emphasise the importance of thorough pain assessment in all persons presenting with CLUs, and especially in all persons reporting ulcer related background pain, to provide effective pain management. Persons with CLUs might need a variety of treatment strategies including analgesics (aimed at both nociceptive and neuropathic pain) and non-medical treatment aimed at chronic pain conditions. Pain management should be a high priority in wound management to avoid negative consequences of pain.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest that could be perceived as prejudicing the impartiality of the research report.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are not available due to privacy or ethical restrictions.

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