

ORIGINAL ARTICLE

Prevalence and factors associated with ulcer-related pain in persons with chronic leg ulcers—an explorative study

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Abstract

Aims and Objectives: The aims of this study were to explore the prevalence of background pain and identify demographic, clinical and psychosocial factors associated with moderate to severe background pain in persons with leg ulcers.

Background: All chronic leg ulcers are potentially painful. Research indicates that 80% of persons with chronic leg ulcers experience wound-related background pain. However, studies on factors associated with pain have small samples and findings are inconclusive.

Design: Exploratory cross-sectional study.

Method: This quantitative study recruited persons with chronic leg ulcers (N = 252) from two wound care clinics using consecutive sampling method. Data were obtained through screening interview, clinical examination and questionnaires. Logistic regression with stepwise backwards elimination was used to identify factors associated with moderate to severe background pain. The STROBE checklist for cross-sectional studies was used for reporting this study.

Results: Background pain was reported by 64% of the participants. Inferential statistical analyses suggest that between 58% and 69% of persons with chronic leg ulcers suffer from this type of pain. Factors associated with moderate to severe pain were older age, female gender, reduced sleep quality and diminished health status. In the final model, reduced sleep quality increased the likelihood of having moderate to severe pain in persons with good health status while not in persons with diminished health status.

Conclusion: Ulcer-related background pain is common in persons with chronic leg ulcers. Older females reporting insomnia symptoms also had increased risk of moderate to severe ulcer-related background pain. These participants also perceived their health status to be better.

Relevance to clinical practice: This study demonstrates that ulcer-related background pain and associated factors needs more attention in clinical practice. Furthermore, nurses and other healthcare professionals should integrate biopsychosocial strategies to assess and manage ulcer-related background pain.

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KEYWORDS

biopsychosocial pain model, chronic leg ulcer, pain, pain prevalence, ulcer-related pain

What does this paper contribute to the wider global clinical community?

- Ulcer-related background pain is a common and significant problem that needs to be addressed in clinical practice.
- The results suggest that nurses and other healthcare providers should be especially aware of pain in older females with insomnia symptoms and perceived good health status.
- This study demonstrates the need for an individual and holistic pain assessment of all persons presenting with a chronic leg ulcer to identify those in need of pain management.

1 | INTRODUCTION

Leg ulcers are hard-to-heal wounds localised on the lower leg or foot commonly caused by venous insufficiency, arterial insufficiency, diabetes and rheumatoid arthritis (Tollow & Ogden, 2019). The chronicity of wounds is defined as a failure 'to proceed through an orderly and timely process to produce anatomic and functional integrity' (Lazarus et al., 1994). The prevalence of chronic leg ulcers in the general population is estimated to be 1.5 per 1000 persons (Martinengo et al., 2019). Since the incidence of wounds rise with age, the prevalence is likely to rise as the population ages (Atkin et al., 2019). All types of chronic leg ulcers, irrespective of pathology, are associated with a negative impact on patients' physical and psychosocial function and health status which may result in a significant decline in quality of life (Cunha et al., 2017; Franks & Morgan, 2003; Herber et al., 2007). In addition, chronic wounds are a major financial burden to the society (Olsson et al., 2019). Finally, research report that all chronic leg ulcers are potentially painful (WUWHS, 2007; Zaidi et al., 2019). Most available research on ulcer-related pain focus on procedure related pain. Ulcer-related background pain, and factors associated with this pain have not been adequately studied.

2 | BACKGROUND

Pain is defined as 'An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage' (IASP, 2020). This definition covers both physical and emotional components of the pain experience and reflects the definition that 'pain is whatever the experiencing person says it is' (McCaffery and Beebe, 1996). Persons with chronic leg ulcers may experience various types of pain. Ulcer-related pain can be nociceptive, neuropathic or inflammatory in nature, as well as acute and/or persistent (White, 2008; Woo & Sibbald, 2008). The World Union of Wound Healing Society (2004) classifies ulcer-related pain as background, incident, procedural and operative pain. Ulcer pain can be caused by the underlying pathology of the leg ulceration and the wound itself, various daily activities, the ulcer treatment, as well as complications such as skin irritation and infection (Renner et al., 2014).

The present study focusses on ulcer-related background pain defined as pain related to wounds experienced in everyday life (other than procedural/operative pain) (Leren et al., 2020). This type of pain is highly prevalent and reduces quality of life (Olsson et al., 2019). A recently published systematic review and meta-analysis reported that up to 80% of persons with chronic wounds experience mild to moderate pain (mean pain intensity of 4 out of 10, 95% CI 3.5, 4.5) between dressing changes (Leren et al., 2020).

According to the existing literature, several demographic and clinical factors that are associated with pain and common across the general population and in persons with ulcers. Female gender (Fillingim et al., 2009), older age (Gibson & Farrell, 2004) and reduced quality of life (Breivik et al., 2006) are factors typically associated with more severe pain in the general population. Female gender (Guarnera et al., 2007), poorer health status (Guarnera et al., 2007; Renner et al., 2014), disturbed sleep (Hellström et al., 2016), as well as wound aetiology (Domingues et al., 2016; Guarnera et al., 2007; Paul, 2013) and size (Salveti et al., 2014) are factors associated with presence of or more severe ulcer-related pain in persons with chronic ulcers. However, other studies found no such association between ulcer-related pain and female gender (Domingues et al., 2016; Renner et al., 2014; Salvetti et al., 2014), or age (Domingues et al., 2016; Renner et al., 2014; Salvetti et al., 2014). Clearly, the literature on factors associated with ulcer-related pain is inconclusive, and typically small and underpowered studies show no significant associations among relevant factors and ulcer-related pain. Further exploration is warranted to identify risk factors for vulnerable patient groups, so that adequate prevention and management of pain can be provided.

In an e-Delphi study from 24 countries and 360 experts, pain management is listed as one of the top educational priorities in wound care (Cowman et al., 2012). While there are differences in nurses' legislated scope of practice across nations and continents, nurses have an overall responsibility to ensure that persons experiencing pain are adequately assessed and provided with effective pain management (American Nurses Association, 2018). Furthermore, pain assessment and management are identified as a main category of the 'wound management and assessment' area for registered nurses providing care for chronic wounds (Kielo et al., 2019). However, wound care researchers report that persistent ulcer-related pain is

either dismissed by healthcare providers or inappropriately assessed (Frescos, 2018; Green et al., 2018). Presumably, lack of knowledge (Green et al., 2018) or time (Frescos, 2018; Green et al., 2018) may be reasons for inadequate pain assessment. Increased knowledge about ulcer-related background pain and associated factors can support nurses in the provision of holistic and person-centred care to persons with chronic leg ulcers.

There is a need for larger and methodologically sound studies to provide research-based knowledge and identify risk factors of ulcer-related background pain and vulnerable persons. Therefore, the objectives of the present study are to explore the prevalence of background pain, and identify the demographic, clinical and psychosocial factors associated with moderate to severe background pain.

3 | METHOD

3.1 | Design and recruitment

This exploratory cross-sectional study used a consecutive sampling method to recruit participants who attended out-patient wound clinics. Participants were approached and recruited on the day of a scheduled appointment. Inclusion criteria were as follows: (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 comprehension difficulties. Exclusion criteria included the following ulcer causes: burns, cancer, radiation treatment, pressure due to immobility and immunological factors. This study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guideline (Von Elm et al., 2014) (see Data S1).

3.2 | Sample size and data collection

A traditional power analysis was not performed for this study, since there were scarce data on the prevalence of background pain in persons with chronic leg ulcers at the time of recruitment. However, we aimed at recruiting at least 170 respondents to be able to explore the association of 6–8 factors with moderate to severe pain. We assumed a small proportion of missing data and a response-rate of approximately 70%. To reach the sample size, we collected data at two wound care outpatient clinics in South-Eastern Norway over a period of 22 months (from March 2017 to December 2018). Information was gathered by means of screening interviews, clinical examinations and self-administered questionnaires.

3.2.1 | Screening interview

An initial screening interview with each patient was carried out by one of the authors (LL), and took place before scheduled appointment at the wound care clinic. Participants were screened for

presence and type of wound pain. All participants were asked 'Do you experience any pain in relation to your ulcer?'. If participants confirmed having pain, the following questions were posed: 'Do you experience wound pain in relation to dressing change?' and 'Do you experience wound pain unrelated to dressing change?'. These three questions were answered using a yes-no format. Data on wound duration and comorbidities was also gathered in the brief interview.

3.2.2 | Clinical examination

During the scheduled appointment at the clinic, a medical doctor assessed the ulcer, and stated the diagnosis (i.e., venous leg ulcer, diabetic foot ulcer, traumatic ulcer, unspecified ulcer). One of the authors (LL) performed all clinical wound examinations and collected data on wound characteristics to avoid inter-rater variability. Wound size was estimated by measuring the width (millimeters at the widest) and height (millimeters at the highest) of the wound. The area was calculated using the formula for an ellipse.

3.2.3 | Questionnaires

All participants received a battery of self-report questionnaires on the day of recruitment. They were asked to answer the questionnaires the following day and return them by mail in a pre-paid envelope. The questionnaires contained items regarding demography, insomnia symptoms and health status. Participants with wound-related background pain also received questionnaires regarding pain.

Demography

Information was collected on age, gender, work situation, education, living arrangements and ethnicity.

EuroQol Visual Analogue Scale (EQ VAS)

The EQ VAS (0–100) was used to obtain information on the respondents' self-reported health status (Oppe et al., 2007). Higher scores indicate better self-perceived health status. The Norwegian translation of the EQ-5D, including EQ VAS, has demonstrated satisfactory measurement properties (Solberg et al., 2005). The original English version of the EQ VAS has been used in studies of persons with chronic leg ulcers (Renner et al., 2014). Missing values in EQ VAS ($n=3$) were replaced by mean imputation.

Insomnia Severity Index (ISI)

The ISI is a brief self-report instrument measuring the patient's perception of their sleep. The ISI targets the subjective symptoms and consequences of insomnia as well as the degree of concerns or distress caused by those difficulties (Bastien et al., 2001; Morin et al., 2011). Its content corresponds in part to the diagnostic criteria of insomnia (Helsedirektoratet, 2016). Each of the seven items in ISI is rated on a 0–4 scale, where zero indicates no problem and four indicates severe problems. The total score ranges

from 0 to 28. The total score is interpreted as follows: absence of insomnia (0–7), sub-threshold insomnia (8–14), moderate insomnia (15–21) and severe insomnia (22–28) (Bastien et al., 2001). The ISI has been translated into several languages and has demonstrated acceptable psychometric properties in studies of the general population with primary insomnia or normal sleeping (Bastien et al., 2001). The Norwegian version of the ISI is widely used, and has demonstrated satisfactory validity (Filosa et al., 2020). Missing values in ISI were replaced by median of nearest point (in total nine individual items). The Cronbach's alpha for ISI was .92 in this study.

The Brief Pain Inventory (BPI)

The BPI is a self-report questionnaire regarding pain characteristics.

The 0 (no pain) to 10 (worst pain imaginable) numeric rating scale (NRS) for worst pain in the last 24 hours was used to gather information about the intensity of ulcer related pain (Cleeland, 2009). The translated Norwegian version of BPI has been validated for use in persons with cancer and osteoarthritis, and has demonstrated good validity and reliability (Gjeilo et al., 2007; Jelsness-Jørgensen et al., 2016; Kapstad et al., 2010; Klepstad et al., 2002). Studies have used the English version of the BPI to assess wound-related pain (Pieper et al., 2013). For the purpose of this study, the BPI was linguistically adjusted to specifically assess ulcer related pain by replacing the word 'pain' with 'ulcer related pain' throughout the questionnaire. The BPI was scored according to the official user guide (Cleeland, 2009). In the analysis, we used pain intensity as a dichotomised variable, no and mild pain (NRS 0–3) versus moderate to severe pain (NRS \geq 4). This cut-off point is in line with previous research of pain intensity (Kapstad et al., 2008).

3.3 | Ethical considerations

The Norwegian Regional Ethical Comity South East Norway approved the study (REC number 2016/1236). In addition, the Data Inspectorate, the research managers and the heads of department at the local hospitals approved the study. Participants were informed about the aims and procedures of this study, and written informed consent was obtained from all participants before inclusion. They were informed that the information they provided would be anonymised in publications, and they could withdraw from the study at any time before publication of the study.

3.4 | Analysis

Descriptive statistics were presented as frequencies with proportions for categorical variables, as means with standard deviation (SD) for normally distributed continuous variables and as medians with interquartile range (IQR) for skewed continuous variables. Comparison of responders versus non-responders in the sample was performed using t tests and chi-squared tests.

To identify factors associated with moderate to severe wound related background pain, we performed logistic regression analyses. The BPI item worst ulcer-related pain (0–10 NRS), dichotomised as moderate to severe pain (NRS 4–10) versus no or mild pain (NRS 0–3), was used as the dependent variable. Participants reporting no wound-related background pain in the screening interview did not receive the BPI in the battery of questionnaires and were therefore scored as 0 on this item. Variables considered for inclusion in the model were factors that were deemed clinically important, or that had a significant association with chronic pain in previous studies. Both univariable and multivariable regression analyses were performed. Results were presented as odds ratios (ORs) with 95% confidence intervals (CIs) and p values. Due to the restricted sample size (75 individuals with moderate to severe pain), we included no more than eight factors in the multivariable model. The included variables were age (per 10 years), gender (male versus female), health status (EQ VAS 0–100), sleep quality (ISI total score 0 – 28), wound diagnosis (venous versus diabetic versus all others), wound size (cm²) and wound duration (weeks). No multicollinearity between the variables was observed. We used stepwise backwards elimination with $p = 0.157$ as criteria (corresponding to *Akaike's Information Criteria*) to obtain a subset of sociodemographic variables that were associated with moderate to severe wound-related background pain. In the final model, we tested for two-way interactions between the included variables. Because of the complexity in interpretation of odds ratio in interaction terms, a significant interaction is presented by an interaction plot.

All tests were two-sided, and with significance level of 5%. Data were mainly analysed using Statistical Package for the Social Sciences (SPSS) version 26. For the purpose of creating the interaction plot Stata 16.0 was used (State College, Tx, USA).

4 | RESULTS

4.1 | Response rate

A total of 279 persons were invited to participate in the study, where of 252 persons accepted and signed the written consent form. The main reason for declining participation was lack of energy. All 252 participants took part in the screening interview and the clinical examination. The questionnaire was returned by 192 participants, leaving a response rate of 69%. Non-responders and responders were compared on important sociodemographic (i.e., age, gender) and clinical variables (i.e., number of comorbidities, presence of ulcer-related background pain), and the groups did not differ significantly (Table S1).

4.2 | Demographic data

The mean age of the total sample was 74.4 years (SD 12.8). The sample consisted of equal parts of men and women. One third lived alone, and two thirds were not working (i.e., on sick leave, retired) (Table 1).

4.3 | Clinical- and wound characteristic

All participants had at least one active wound located at the leg, ankle or foot. The median wound duration was 14.5 weeks (IQR 8–26), and the median wound size of the largest lesion was 1.2 cm² (IQR 0.2–4.7). Unspecified ulcer in lower extremities (ICD-10 diagnosis code L97) was the most frequent wound diagnosis (27%). A total of 76% reported more than one comorbidity. The most frequent comorbidities were coronary diseases, including hypertension and atherosclerosis (77%), painful conditions such as musculoskeletal pain (50%), and diabetes (35%) (Table 2).

4.4 | Prevalence of ulcer related background pain

Ulcer-related background pain was reported by 64% (95% CI 58–69) in the total sample (N = 252). Of those returning the questionnaire (N = 192), 42% reported no ulcer-related background pain, 19% reported mild ulcer-related background pain, while 39% reported moderate to severe ulcer-related background pain during the last 24 h (Figure 1).

4.5 | Factors associated with moderate to severe ulcer related background pain

In univariate analyses, older age, female gender and reduced sleep quality were significantly associated with moderate to severe wound-related background pain (Table 3). After backward elimination, age was associated with pain (OR per 10 years 1.47, 95% CI 1.10–1.97), as well as female gender (OR 2.44, 95% CI 1.28–4.68). Quality of sleep was also associated with the risk of moderate to severe pain (OR for 1 unit increase 1.13, 95% CI 1.06–1.20). Health status was not significant in the univariate analysis but reached significant in the multivariable analysis (OR 1.02, 95% CI 1.00–1.04). The pseudo R² indicated that the model explained 13% of the variance in the variable moderate to severe pain. In the final model, we found an interaction between health status and sleep quality. The interaction plot demonstrates that sleep quality has a modifying effect on health status, that is for persons with diminished health status the importance of sleep was minor, while for persons with better health status the sleep quality has great impact of the predicted probability of moderate to severe pain (Figure 2). The ORs of age and gender were similar in the models with and without the interaction term.

5 | DISCUSSION

This study estimated that the pain prevalence in the population of persons with chronic leg ulcer was between 58% and 69%. This confidence interval is relatively narrow and similar to the prevalence of 60% found in descriptive studies in a recent meta-analysis (95%

TABLE 1 Demographic data of total sample (N = 252) and respondents stratified by pain (N = 192).

	Total sample N = 252		Respondents stratified by pain N = 192			
	n	%	No/mild pain N = 117		Moderate/ severe pain N = 75	
	n	%	n	%	n	%
Age						
<49	10	4.0	8	6.9	1	1.3
50–59	23	9.1	13	11.1	5	6.7
60–69	42	16.7	21	17.9	10	13.3
70–79	84	33.3	41	35.0	27	36.0
80–89	69	27.4	26	22.2	25	33.3
>90	24	9.5	8	6.8	7	9.3
Total	252	100	117	100	75	100
Gender						
Male	128	50.8	72	61.5	26	34.7
Female	124	49.2	45	38.5	49	65.3
Total	252	100	117	100	75	100
Marital status						
Single	34	13.5	25	21.4	9	12.0
Married/cohabitant	112	44.4	69	59.0	43	57.3
Widowed	46	18.3	23	19.7	23	30.7
Total	192	76.2	117	100	75	100
Educational level						
Primary school	72	28.6	40	34.2	32	42.7
Secondary school	66	26.2	41	35.0	25	33.3
University <4 years	35	13.9	23	19.7	12	16.0
University >4 years	15	5.9	11	9.4	4	5.3
Total	188	74.6	115	98.3	73	97.3
Work situation						
Working	19	7.5	11	9.4	8	10.7
Retired/sick leave	171	67.9	105	89.7	66	88.0
Total	190	75.4	116	99.1	74	98.7
Living arrangements						
Alone	76	30.2	45	38.5	31	41.3
With spouse/other family	116	46.0	72	61.5	44	58.7
Total	192	76.2	117	100	75	100
Ethnicity						
Norwegian	187	74.2	115	98.3	72	96.0
Other	4	1.6	2	1.7	2	2.7
Total	191	75.8	117	100	74	98.7

CI 44%–75%) (Leren et al., 2020). The pain prevalence found in this study is, however, lower than the prevalence of 90% demonstrated in effect studies from the same meta-analysis (Leren et al., 2020). Note that there is a great variation in how ulcer related pain is assessed,

TABLE 2 Clinical- and wound characteristics of the total sample (N = 252).

	Median	IQR	Mean	SD	n	(%)
Wound diagnosis						
Unspecified (ICD-10 code L97)					67	26.6
Diabetic					53	21
Venous					50	19.8
Other					82	32.6
Wound duration (weeks)	14.5	8-26				
Wound size (cm ²)	1.19	0.20-4.71				
Number of comorbidities			3.1	1.48		
Type of comorbidities						
Coronary disease					193	76.6
Other painful conditions					125	49.6
Diabetes					87	34.5
Malnutrition					68	27
Renal disease					47	18.7
Cancer (previous or present)					44	17.5
Arthritis					43	17.1
Stroke					22	8.7
Asthma/COPD					20	7.9
Pain intensity (BPI, item 3, 0-10 NRS)	2.5	0-6				
Sleep quality (ISI, total score, 0-28)	7	3-12				
Health status (EQ VAS)			60.2	21.0		

Abbreviations: BPI: Brief Pain Inventory, COPD: Chronic Obstructive Pulmonary Disease, NRS: Numeric rating scale, ISI: Insomnia Severity Index, IQR, interquartile range; EQ VAS: EuroQol Visual Analogue Scale item; SD, standard deviation.

and studies are rarely explicit on the type of ulcer pain they have investigated. In fact, persons with ulcers are likely not aware of the differentiation between background and procedural ulcer pain, unless this differentiation is explicitly addressed. We believe that the screening procedure of ulcer-related background pain used in this

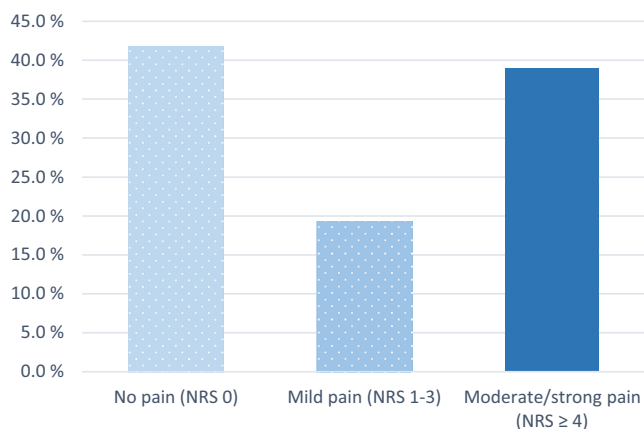


FIGURE 1 Ulcer-related background pain intensity, based on questionnaire respondents (N = 192). [Colour figure can be viewed at wileyonlinelibrary.com]

study, provides a lower but more precise prevalence rate of background pain in a sample of persons with various types of leg ulcers.

Of those returning the questionnaire (N = 192) almost one third reported moderate to severe pain intensity. In this study, we grouped the NRS pain intensity score into no pain, mild pain and moderate to severe pain. This procedure is in line with previous research on pain intensity cut points (Kapstad et al., 2008). In most studies of pain in persons with chronic leg ulcers, prevalence of pain and mean pain intensity scores are reported (Leren et al., 2020). From a clinical perspective, it is often more relevant to look at the percentage share of the persons experiencing moderate to severe pain. While people often tolerate mild pain and do not need analgesics, moderate to severe pain can reduce quality of life and requires pain management including both non-opioids and weak or strong opioids. There may be numerous reasons for the high percentage of severe pain in the present study, but inadequate pain management is probably a major contribution. Research indicates healthcare professionals do not comply with well-established guidelines for best practice of wound care when it comes to pain assessment (Franck & Bruce, 2009; Frescos, 2018), and are insecure about the optimum pharmacological management of non-malignant pain in older persons (Barber & Gibson, 2009). In addition, stoicism and fear of addiction among

	Univariate analysis			Multivariate analysis		
	OR	CI (95%)	p	OR	CI (95%)	p
Age (per 10 years)	1.38	1.08–1.76	0.01	1.46	1.10–1.94	<0.01
Female gender ^a	3.02	1.65–5.52	<0.01	2.44	1.28–4.68	<0.01
Health status (EQ VAS)	1.01	0.99–1.02	0.65	1.02	1.00–1.04	0.02
Sleep quality (ISI)	1.09	1.04–1.15	0.01	1.13	1.06–1.20	<0.01
Wound diagnosis ^b						
Venous	1.39	0.66–2.90	0.38			
Diabetic	0.87	0.42–1.81	0.71			
Wound size (cm ²)	1.10	0.99–1.22	0.08			
Wound duration (weeks)	0.99	0.97–1.01	0.25			

Abbreviations: EQ VAS: EuroQol Visual analogue scale, ISI: Insomnia Severity Index. OR: Odds Ratio, CI: Confidence Interval.

^amale gender served as reference group; ^ball other wound diagnosis (other and unspecified) served as reference group

TABLE 3 Logistic regression models of factors significantly associated with moderate to severe wound-related background pain (N = 192).

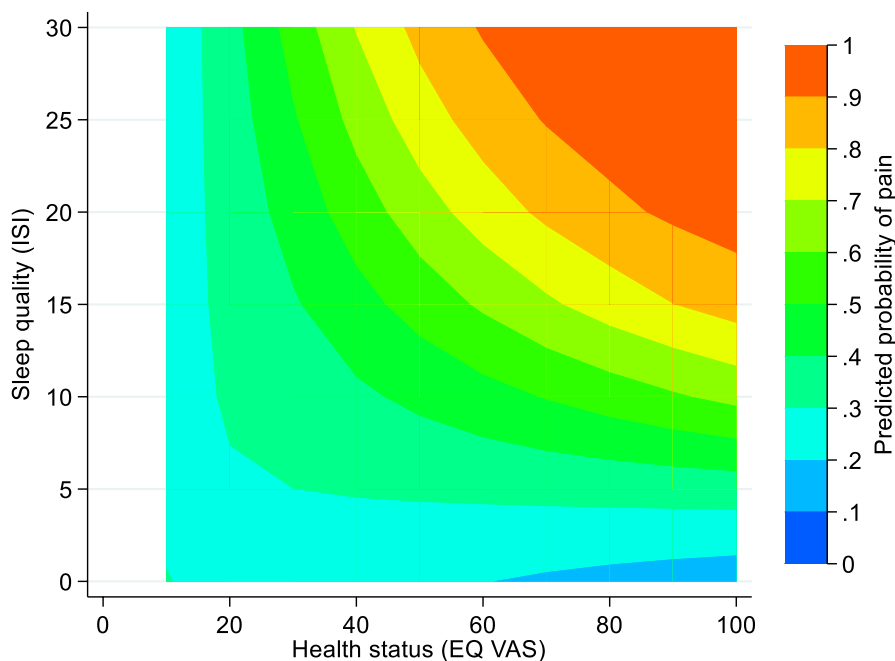


FIGURE 2 Plot demonstrating the interactions effect between health status (EQ VAS) and sleep quality (ISI) for moderate to severe ulcer-related background pain. [Colour figure can be viewed at wileyonlinelibrary.com]

patient with chronic venous ulcers, may lead to a tendency to take analgesics less frequently or at a lower dose than prescribed (Sale et al., 2006). Regardless, findings from this study indicate that there is a need to address pain management in chronic ulcer wound care.

In the univariate analysis in the present study, female gender, older age and more insomnia symptoms were factors associated with moderate to severe ulcer-related background pain. The association between gender and pain is consistent with the previous study on patients with chronic ulcers by Guernera and colleagues (2007), and the association between age and pain is supported by previous research in the general population (Gibson & Farrell, 2004). The reason for these associations not being more apparent in previous studies on chronic ulcers, might be due to small sample sizes as well as using different pain intensity scores.

In the multivariate analysis, older females reporting insomnia symptoms also have increased risk of having moderate to severe ulcer-related background pain. Interestingly, these participants also perceived their health status to be better. We also found an interaction between health status and insomnia symptoms in the multivariate analysis. We hypothesise that the importance of sleep depends on the level self-perceived health status when investigating the risk of moderate to severe ulcer-related pain. This means that for people with diminished health status, sleep does not have a significant impact. It is possible that diminished health status has such great impact on a person's life, that insomnia symptoms becomes secondary. However, if a person reports good health status, insomnia symptoms becomes more noticeable and in turn influence the likelihood of having moderate to severe pain. Note that our cross-sectional data offer

limited information about the mechanism affecting the relationship between insomnia symptoms, health status and moderate to severe pain. This relationship should be subject for further research. Despite the limited knowledge about the mechanisms in play, we would assert that it is imperative to screen for insomnia symptoms and impact on health status in persons presenting with chronic leg ulcers. The findings are a reminder that nurses need to pay attention to sleep and pain in persons reporting good health status, as well as those reporting diminished health status.

Unlike previous studies of factors associated with ulcer-related pain, we found no significant association between several biological factors (i.e., wound diagnosis, ulcer size, ulcer duration) and moderate to severe ulcer-related background pain. Even though there are differences in the pathologies and clinical characteristics of different types of chronic leg ulcers, all chronic leg ulcers are associated with a profound impact on persons' physical, functional and psychological status (Cunha et al., 2017; Franks & Morgan, 2003; Herber et al., 2007). Pain is a biopsychosocial phenomenon (IASP, 2020), and it is acknowledged that the size and severity of an injury is not always related to the pain experienced (Chapman et al., 2000). The experience of pain related to a chronic ulcer can be affected by biological, psychological and social factors (Gatchel et al., 2007). Note that the proposed model only explains a small part of the variance in the sample. It is reasonable to assume that psychological and social factors account for a substantial part of the remaining variation. In addition, the lack of clear associations with regards to the biological variables demonstrates the need for an individual and holistic pain assessment of all persons presenting with a chronic leg ulcer to identify those in need of pain management.

Some limitations of this study need to be addressed, and generalisation of results is not straight forward since we recruited only hospital outpatients. Our sample may therefore not be representative of a community sample of persons living with chronic leg ulcers. Additionally, because of the explorative nature of this study, we included participants with a variety of wound diagnosis, and almost 60% had 'unspecified' or 'other' wound diagnoses. This makes generalisation to one specific wound patient group, as well as comparison of research findings, a challenging task. However, from a clinical perspective the participants in the present study do represent the population attending outpatient clinics. Even with careful systematic assessment, wound diagnostics can be challenging in cases with multiple underlying factors, borderline diagnostic indicators and mixed aetiologies (Gupta et al., 2017). The heterogeneity in ulcer diagnosis is representative for the clinical practice, making the results from this study relevant. However, the lack of diagnostic specificity is the reason why we did not explore these groups (others and unspecified) as risk factors for moderate to severe ulcer-related background pain in the regression analyses.

Furthermore, a cross-sectional design only allows for observing factors associated with moderate to severe ulcer-related background pain, and determining an established causal relationship is not possible. In the future, the association between gender, age,

health status, insomnia symptoms and pain should be explored using longitudinal data. In addition, more confounding factors, such as socioeconomic status should be included and adjusted for. For instance, in previous studies, education, income and occupation were associated with ulcer-related pain (Domingues et al., 2016; Salvetti et al., 2014). However, the variables describing socioeconomic status in our study were not suitable to accentuate distinctions in the population.

Finally, the use of a single variable of pain intensity to assess persistent ulcer-related pain is questionable, since the assessment of persistent pain requires a holistic approach, including numerous pain characteristics, physical- and psychological factors (Tauben & Stacey, 2020). However, for the purpose of demonstrating associated factors we found pain intensity to be the best available and comparable option. In addition, the use of the 3rd item in the BPI (strongest ulcer-related pain in the last 24 h) might have led to higher pain intensity reports, compared to studies using the mean pain intensity score. However, the worst pain intensity item presumably provides information of the most bothersome pain and gives a stronger indication of a person's need for pain management.

6 | CONCLUSIONS

This study shows a high prevalence of ulcer-related background pain in persons with chronic leg ulcers. As many as 29% reported having moderate to severe background pain. These findings indicate that pain assessment and management still need more attention in ulcer care. Furthermore, our analysis indicates that being female of older age, as well as having better health status and more insomnia symptoms, enhance the risk of having moderate to severe ulcer-related background pain. The intricate relationship between health status, insomnia symptoms and moderate to severe pain is interesting, but further research is needed. This study demonstrates the need for an individual and holistic pain assessment of all persons presenting with a chronic leg ulcer to identify those in need of pain management.

7 | RELEVANCE TO CLINICAL PRACTICE

This study highlights that ulcer-related background pain is a common and ongoing problem in persons with chronic leg ulcers. Awareness of the extent of ulcer-related background pain is the first step—but alone not sufficient to improve practice. Nurses and other health-care professionals need to integrate biopsychosocial strategies to assess ulcer-related background pain. Particular attention must be paid to those patients who demonstrate a greater risk of having moderate to severe ulcer-related pain, such as older females with insomnia symptoms and good perceived health status. The presence of a chronic ulcer, as well as the aforementioned risk factors, should draw clinician's attention to assess pain, evaluate the need of pain management, and offer proper pain-relieving interventions.

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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.

AUTHOR CONTRIBUTION

All authors contributed significantly in the conception and design of the study. Leren performed the data collection. Leren, Falk and Ljoså performed the data analysis. Leren and Ljoså drafted the work. Eide, Johansen and Falk revised it critically for important intellectual content. All authors read and approved the final manuscript. All authors agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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