

## CLINICAL REPORT

# Association of Pain Level, Health and Wound Status in Patients with Chronic Leg Ulcers

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**Pain is a ubiquitous problem in patients with chronic leg wounds. The pain may be caused by the underlying pathology of the leg ulceration, the wound, wound treatment, or complications such as skin irritation around the ulcer. The objectives of this research were to evaluate the level of suffering endured by patients because of their ulcer-related pain, and to evaluate whether and how this pain is treated. In addition, to determine whether this pain influences quality of life and health status. In 2010, data were collected in order to characterize the patients by socio-demographic facts, such as age, gender, co-morbidity, pathogenesis of the wound, wound status of new patients, wound pain, and use of analgesics. In addition, modified EQ-5D questionnaires were distributed with additional questions concerning pain experience, treatment, and general health status. Of 103 patients, 45 were male and 58 female. Mean age was 67.8 years (males 65 years, females 70 years). Up to 69% had leg ulcerations due to vascular disease. Out of the 103 distributed questionnaires, 49 were returned and evaluated. Analysis showed that 82% of these patients reported wound-related pain, and 42% estimated their analgesics as not sufficiently pain relieving (mean value of the visual analogue scale (VAS) 4.9). Mean health status was 50.5 (maximal health status 100). Patients with a pain value  $\geq 5$  showed a lesser mean health status (42.2) than patients with a pain value  $< 5$  (60.3). The proportion of patients receiving no, or only weak, analgesics was nearly the same for patients with  $VAS \geq 5$  and with  $VAS < 5$ . Further research in pain therapy is of utmost importance to improve the quality of life of patients with chronic wounds. *Key words: outpatient wound-care clinic; wound pain; wound pain therapy; health status; socio-demographics; wound status; venous ulcers.***

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Pain is a frequent symptom in elderly patients (1), especially in those with chronic leg ulcerations (2–4). The exact prevalence of pain is unknown, but recent studies have reported that 17–65% of patients experience severe

or continuous pain associated with a leg ulcer (2, 3). There are different pathologies that might cause pain associated with leg ulcerations (e.g. rheumatoid arthritis, vascular disease, and diabetes). In addition, pain might result directly from the wound (i.e. through inflammatory processes from the injury), neural irritation (e.g. by ischaemia, infection, or inflammation), or complications such as infection, skin maceration, contact dermatitis, or wound treatment (4, 5). The objectives of this research are to evaluate the level of suffering that patients endure because of their ulcer-related pain, and to evaluate whether and how this pain is treated. A further aim was to determine whether this pain influences quality of life and health status in patients in our outpatient wound-care clinic.

## MATERIALS AND METHODS

### *Patients and organization of the outpatient wound-care clinic*

In 2010, data were collected for all patients, in order to characterize patients by socio-demographic factors, such as age, gender, co-morbidity, pathogenesis of the wound, wound status of new patients, wound pain, and use of analgesics. In addition, modified EQ-5D questionnaires were distributed with additional questions concerning pain experience, treatment, and general health status.

A total of 103 patients from our outpatient wound-care clinic within the Clinic of Dermatology in Leipzig, Germany, participated in this evaluation. The consulting hours were held in the afternoon for 4 days a week. With continuous cooperation with the vascular surgeons and endocrinologists at the Universitätsklinikum Leipzig, we referred patients with confirmed or suspected diagnoses of ulcerations due to diabetes or peripheral arterio-vascular disease to those specialists. In general, only dermatologists referred all patients in our special wound-treatment consulting hours. Patients receiving treatment for their wounds in other parts of the clinic (e.g. surgical wounds) were not included in this analysis.

### *Modified EQ-5D questionnaire*

To evaluate pain and prescription of analgesics in more detail, we distributed an anonymous, modified EQ-5D questionnaire to all 103 patients, in order to record health status, quality of life, and pain symptoms of those patients, and asked them to complete the questionnaire at their first visit. This questionnaire also included a numerical visual analogue scale (VAS), and additional questions regarding pain therapy and its effectiveness.

The EQ-5D is a standardized descriptive self-administered questionnaire measuring health-related quality of life (6), which

includes a scale of 0 to 100 for the patient's current health status. The questionnaire contains 5 dimensions (mobility, self-care, daily activities, pain/discomfort, and anxiety/depression), each of which can have 1 of 3 responses. The responses record 3 levels of severity (no problems, some or moderate problems, extreme problems) within a particular EQ-5D dimension. Lastly, patients have to compare health levels today vs. one year ago. Additional questions were added to the existing questionnaire regarding the patient's age, sex, type of analgesics and their dosage, how frequently they took analgesics, who prescribed those analgesics, and an overall rating if those analgesics were pain relieving (yes, no, partial). The overall rating was combined with a detailed pain rating that included a numerical VAS. With these modifications, it was possible to correlate the use of analgesics with the health status of the patients, even though the questionnaires were answered anonymously.

#### Measurements of immobility and wound area

Immobility was measured independently from the questionnaire by the treating dermatologist. The following criteria were used: (i) patients were wheelchair-dependent; (ii) patients were hindered by a (rolling) walker; and/or (iii) spent > 50% of daily life sitting or lying down. If one or more of these definitions were true, we counted the patient as immobile for this evaluation.

Planimetric wound measurements were normally performed with Visitrak<sup>®</sup>, by secondary evaluation of an electronic photograph, or by planimetric calculation of the wound area.

For analysing possible correlations between pain levels and health status, we determined the correlation coefficient ( $R^2$ ), where high values of  $R^2$  signal a stronger correlation between 2 variables than do low values (maximum  $R^2=1$ ).

## RESULTS

#### Socio-demographic data: age, gender and co-morbidity

Of 103 patients, 45 were men and 58 women. The mean age was 67.8 years (mean age of males 65 years, mean age of females 70 years). Forty-six of the 103 patients were in our outpatient wound-care clinic for the first time. Approximately two-thirds of patients lived within the city region of Leipzig. Approximately 8% of patients travelled to our outpatient clinic from a distance of 70–105 km.

Cardiac co-morbidities (arterial hypertension, cardiac dysrhythmia, cardiac failure, myocardial infarction, status post-apoplexy) were most frequently observed (see Table I). Each patient could have one or more co-morbidities; therefore the cumulative percentage is >100%. Eight of 12 patients with auto-immunological concomitant diseases had rheumatoid arthritis, but this was not always the cause of their ulceration. In approximately 50% of all patients immobility was caused by their age, co-morbidity, and/or ulceration in general. The possibility of extensive outpatient surgical debridement was reduced in approximately 10% of the patients due to different forms of anaemia (iron deficiency, vitamin B12 deficiency, unclear) or anticoagulation.

In 2010, approximately 8% of the patients were previously or currently colonized with multi-resistant bacteria, such as methicillin-resistant *Staphylococcus*

Table I. Co-morbidities, main pathogenesis of the treated ulcerations and subgroups of the ulcerations due to a vascular component in 2010

	Patients %
Co-morbidities <sup>a</sup> (n=103)	
Cardiovascular	70
Thrombosis/embolism	17
Surgical pre-treatment	17
Rheumatic/immunological	12
Anti-coagulation	11
Erysipelas	10
Total endoprosthesis	8
Problematic bacteria	8
Anaemia	8
Renal failure	8
Lung disease	6
Thrombophilia	5
Immunosuppression	1
Main pathogenesis (n=103)	
Vascular leg ulcer	69
Post-traumatic	14
Immunological	6
Diabetic foot	4
Decubitus	1
Others	6
Subgroups (n=71)	
Venous	49
Venous-lymphatic	15
Arterio-venous	18
Lymphatic	8
Arterial	6
Arterio-lymphatic	3

<sup>a</sup>Each patient could have one or more co-morbidities, therefore the cumulative percentage is > 100%.

*aureus* (MRSA) or *Escherichia coli* with extended spectrum beta-lactamase (ESBL).

#### Wound status and pathogenesis of the wounds

The total group (n=103) showed a mean wound area of 63 cm<sup>2</sup> (median 12 cm<sup>2</sup>) and a mean wound duration of 3.8 years (median 1 year; minimum 3 weeks, maximum 50 years), where the duration could only be estimated by the majority of the patients. New patients (n=46) showed a smaller mean wound area of 48 cm<sup>2</sup> (median 9.5 cm<sup>2</sup>) and a shorter mean wound duration of 2.2 years (median 0.6 years; minimum >3 weeks, maximum 20 years) at their first presentation compared with all patients in 2010 (for details see Table II). The new patients especially showed eczema or inflammation (n=20/46), strong secretion (n=11/46), maceration (n=8/46), and needed initial debridement (n=8/46) of broad fibrinous burden or necrosis of the wound surface.

Pathogenesis was evaluated by the clinical features of the ulcerations in combination with a Doppler/Duplex-ultrasound and a histological examination. The main

Table II. Ulcer area and ulcer duration for all vs. new patients in 2010

	All patients (n=103)	New patients (n=46)
Ulcer area, cm <sup>2</sup>	63 (mean); 12 (median)	49 (mean); 9.5 (median)
Wound duration, years	3.8 (mean); 1 (median)	2.2 (mean); 0.6 (median)

treated ulcerations were vascular-caused leg ulcerations (69 %). The other patients had post-traumatic ulcerations (14%), immunological ulcerations (6%), diabetic foot ulcers (4%), decubiti (1%), and “others” (6%) (for details see Table II). The subgroup of vascular-caused ulcerations ( $n = 71/103$ ) was analysed in greater detail. This analysis discovered venous aetiology in 49% as the single causative factor. Other factors included arterio-venous (18%), venous-lymphatic (15%), only lymphatic (8%), only arterial (6%), and arterial-lymphatic aetiology (3%) for their ulceration (details see Table II). In total, complex ulcerations with divergent and not synergistic influenceable vascular components, such as combined venous (compression) and arterial (limited compression therapy) or combined lymphatic (compression) and arterial (limited compression therapy), were present in 21%; the fraction of mixed ulcerations (including venous-lymphatic ulcerations) in total was 36%.

### Subjective health status and pain

Of 103 patients, 48 reported that they had pain due to their ulceration. Independently of this, we distributed our modified EQ-5D questionnaires (Appendix S1<sup>1</sup>) to all 103 patients. Of these 103 distributed questionnaires, 49 were returned and evaluated. Of those 49 patients, 22 were male and 27 were female, mean age 70.9 years (mean age of men 70.4 years, mean age of women 71.5 years). The results from the EQ-5D questionnaire are shown in Fig. 1. Analysis showed that 33% of patients ( $n = 16/49$ ) felt that their general health status was decreasing (self-estimation within

the EQ-5D) compared with the previous year (see Fig. 1). In 2010, at the time of interviewing with the questionnaire, the mean health status was 50.5 (maximum health status 100).

Forty-three percent ( $n = 21$ ) of patients took analgesics daily, which were prescribed by their general practitioners or their dermatologists (63%). Thirty-six percent ( $n = 18$ ) of patients estimated their analgesics as moderately, but not sufficiently, pain-relieving, with a mean value of 4.9 on the VAS. Twenty-six percent ( $n = 13/49$ ) of patients stated that they rarely (< 1–3 times/month,  $n = 7$ ) or never took analgesics ( $n = 6$ ). The reasons for this were not asked.

Approximately 88% ( $n = 38$ , of 43 who were taking analgesics) could name their prescribed analgesics, with the majority of them being class 1 analgesia (World Health Organization (WHO) classification). Only a few patients ( $n = 4$ ) received a prescription with derivatives of morphine in combination with non-steroidal anti-phlogistics or narcotic drugs.

Eighty-eight percent of patients with a pain value  $\geq 5$  received analgesics. In a sub-analysis, patients ( $n = 26$ ) with a pain value  $\geq 5$  showed a more reduced mean health status (42.2) than patients ( $n = 23$ ) with a pain value  $< 5$  (60.3). However, the number of patients receiving no, or only weakly effective, analgesics was nearly the same for patients with VAS  $\geq 5$  ( $n = 20$ ) and with VAS  $< 5$  ( $n = 19$ ).

Patients without analgesics evaluated their pain as equal to those patients with analgesics (both  $R^2 = 0.47$ ). When separating men and women, the health status differed more in men ( $R^2 = 0.56$ ) than in women ( $R^2 = 0.08$ ) (see Fig. 2;  $R^2 =$  correlation coefficient for men and women: higher values suggest a stronger correlation between 2 variables than lower values of  $R^2$  (maximum  $R^2 = 1$ )). The majority of women evaluated their health status as between 40 and 60, independent of their pain. There was no correlation between age and subjectively perceived pain level ( $R^2 = 0.01$  women/ $R^2 = 0.02$  men).

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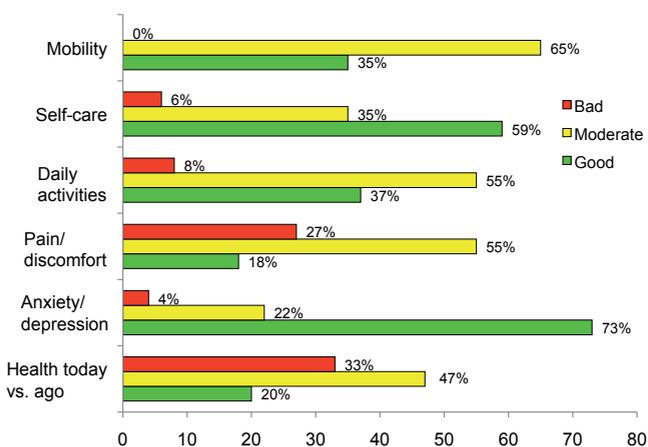


Fig. 1. Evaluation of the standard questions of the self-assessment questionnaire EQ-5D in  $n = 49$  patients in 2010. The questionnaire includes a scale of 0–100 for the patient's current health status. The questionnaire contains 5 dimensions, mobility, self-care, daily activities, pain/discomfort, and anxiety/depression, each of which can take 1 of 3 responses. The responses record 3 levels of severity (no problems, some or moderate problems, extreme problems) within a particular EQ-5D dimension. Lastly, patients have to compare health levels today vs. one year previously.

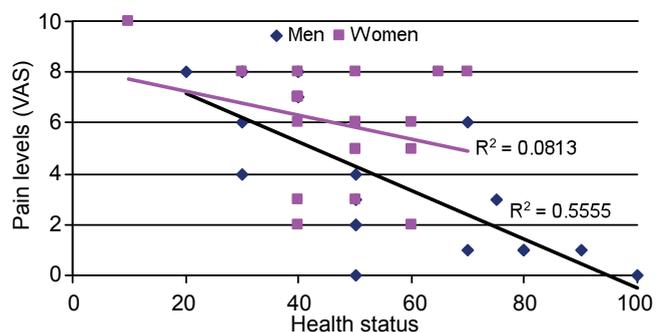


Fig. 2. Correlation of pain levels (visual analogue scale (VAS) results) and health status ((0–100) points in the self-assessment of the questionnaire) for individual patients ( $n = 49$ ). Similar results (VAS/health status) of patients of the same sex are represented as a single spot in the figure in order to facilitate the figure.  $R^2 =$  correlation coefficient for men and women: higher values signalize a stronger correlation between 2 variables than lower values of  $R^2$  (maximum  $R^2 = 1$ ).

Unfortunately, pain levels are subjective and have a wide variance; therefore the overall  $R^2$  is moderate, but the  $R^2$  of 2 similar groups is sufficiently comparable.

## DISCUSSION

Insufficient pain therapy is also documented for other patients with ulcerations (7, 8). In this study, it was found that there was an under-representation of opium-based analgesics. It was not asked whether the reduced use was caused by the patients' anxiety about using opium-based analgesics, or if higher potency analgesics were not prescribed. We expected that patients with high pain levels should have received medication according to the WHO recommendation, but the proportion of patients receiving no, or only weakly potent, analgesics was nearly the same in the group with  $VAS \geq 5$  and patients with  $VAS < 5$ .

This study found that the subjective health status of the patients is reduced by higher pain levels (see Fig. 2). This association might be stronger for men than in women (see Fig. 2). The majority of women evaluated their health status independently of their pain levels, with values between 40 and 60. We hypothesized that this might be due to the fact that women differentiate less, or pain does not play an important role in the evaluation of their general health status.

There are limitations in this pain evaluation because, for example, only 47.5% of all patients returned their pain assessment questionnaire including the EQ-5D. Reasons for non-response may be the complexity of questions, especially for elder and/or senile patients, who might feel overwhelmed by the different tools and questions within the questionnaire, the lack of major pain, or perhaps the minor impact of the disease.

The pathogenesis of the ulceration might also influence how sufficient pain relief can be achieved during the course of treatment (e.g. in arterial ulcers). Therefore, it is important to document combinations of ulcerations more precisely because they can restrict therapy and affect the result of the pain and wound treatment. Those complicating ulcerations were present in up to 25% of patients. With continuous cooperation from the vascular surgeons and endocrinologists at the Universitätsklinikum Leipzig, patients with confirmed or suspected diagnosis of ulcerations due to diabetes or peripheral arterio-vascular disease were referred to those specialists. Therefore, under-representation or lack of wounds caused by vascular-diabetic ulcerations in our outpatient wound-care clinic might be due to those selection efforts when arranging the appointments.

Unfortunately, the mean wound area and wound duration at first presentation illustrate that often after a (too)

prolonged and recalcitrant course of wound healing, patients are referred to special consulting hours. This might not only reduce the chance of complete recovery for affected patients, but also might cause unnecessary pain for those patients. In total, this could increase costs for them and the healthcare system.

Professional pain treatment should be performed by the patient's local physician, and not only in special units for wound treatment where patients are sometimes seen only every 3 months. Concomitant circumstances, such as wound dressings, wound margins, or co-morbidities, might change more quickly with the need to re-evaluate pain medication. Patients reported that travelling long distances was difficult. The EQ-5D questionnaire reported 65% of patients mentioned problems with their mobility; therefore transportation to the outpatient wound-care clinic might be a great obstacle.

The results of this study suggest that it is necessary to improve wound treatment and pain therapy in patients with chronic wounds. Higher pain levels reduce the subjective health status of the patients. The mean wound area and wound duration at first presentation illustrated that patients are referred to special consulting hours after a prolonged and recalcitrant course of wound healing.

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