



Gdansk Wound-QoL Questionnaire: Pilot Study on Health-Related Quality of Life of Patients with Chronic Ulcers with Emphasis on Professional Physician-Patient Relations

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ABSTRACT **Introduction:** Chronic wounds lower health-related quality of life (QoL), as they affect various aspects of life due to pain, odor, tedious treatment, and stigma from society. Implementing proper treatment, where patient is well informed and active is a key for best outcomes.

Objectives: The aim of the study was to evaluate health-related QoL among the patients with chronic ulcers, with the use of new scale Gdansk Wound QoL.

Methods: We enrolled 108 patients who met the inclusion criteria. Before the education on day 0 patients were asked to fill in Gdansk Wound-QoL questionnaire, that was developed in cooperation between dermatologists, general and plastic surgeons, as well as wound nurses, as well as fill the follow-up Gdansk Wound-QoL questionnaire on day 30, which was also the end of the study.

Results: Study participants (N = 108) were on average 76.1 ± 10.8 years and all of whom had a venous ulcer on their lower limbs of average wound area of 10.8 cm^2 . QoL, according to the Gdansk Wound-QoL questionnaire, increased on average by 36.7% after 30 days trial. Moreover, on the follow-up visit 94.4% of the patients stated that their knowledge on the disease has increased and everyone was satisfied with the course of treatment proposed by the current doctor. Furthermore, 44.4% of the study group increased their activity at the end of the study.

Conclusions: This pilot descriptive observational study shows that Gdansk Wound-QoL questionnaire can provide professionals in wound care good feedback on health-related QoL of patients with chronic wounds. This information has the potential to enhance patients well-being and overall comfort.

Introduction

Chronic wounds predominantly afflict the elderly population, affecting approximately 1%-2% of the Western population at least once in their lifetime [1]. These persistent wounds pose a significant threat to the quality of life (QoL) of sufferers due to the enduring pain, unpleasant odor, cumbersome treatment procedures, and societal stigma [2]. Such diminished QoL can lead to various associated health issues, including depression, and hinder patients compliance with treatment plans [3]. Patients frequently express dissatisfaction with the perceived lack of time, empathy, and understanding from physicians, resulting in strained doctor-patient relationships and suboptimal treatment outcomes. Interestingly, studies indicate that patients may prioritize factors such as pain, itching, sleep disturbances, functional limitations, and frustration over mere wound healing, emphasizing the need for a holistic approach to assess QoL [4].

To establish effective doctor-patient relationships and ensure compliance, tailored strategies must be employed. Chronic wound patients, regardless of age, desire understanding and clear communication. Each new patient should be afforded sufficient time for comprehensive examination and detailed explanation of the treatment plan [5]. Empirical evidence demonstrates that well-informed patients, even among the elderly, can adeptly manage dressing changes, reducing the need for frequent specialist visits and minimizing waiting times. The ultimate objective in chronic wound care is to establish a suitable treatment regimen following TIMERS guidelines and educate patients or their caregivers to independently implement these actions [6]. TIMERS - Tissue, Infection/Inflammation, Moisture, Wound edge, Repair/Regeneration, Social, is an acronym that is a wound assessment tool.

Numerous patients express a sense of being overlooked by healthcare providers and grapple with feelings of shame stemming from the psychological ramifications of their condition. Furthermore, they harbor apprehensions about societal scrutiny, enduring pain, or the potential necessity of limb amputation. Guidelines set forth by the European Wound Management Association underscore the crucial role of social determinants in the wound healing process [6]. Embracing a comprehensive approach that identifies patients needs, aligns with their aspirations, and furnishes education to patients and their families is paramount. Communication should be

lucid and accessible, while dressing change techniques ought to be straightforward for patients to execute autonomously. Customizing information dissemination and involvement levels in accordance with patients educational backgrounds and psychophysiological capacities, particularly in cases of dementia or absence of familial support, is essential.

Several QoL questionnaires for chronic wound patients are available, such as Wound-QoL and Cardiff Wound Impact Schedule, comprising 17 and 51 questions, respectively [7,8]. Notably, these questionnaires do not encompass inquiries about patients relationships with the clinic and treating physician or their overall satisfaction with the treatment, irrespective of the treatment outcome.

A plethora of scales assessing the quality of life in patients with chronic diseases exist, aiding in the monitoring of treatment effectiveness. However, there is a notable absence of a unified scale designed for both patients and their caregivers, facilitating the tracking of treatment outcomes over time. Moreover, there is a lack of a comprehensive tool that enables the evaluation of the impact of the patient-physician relationship on the patients QoL.

Objectives

The aim of this study was to evaluate the Health-Related QoL (HRQoL) of patients with chronic ulcers using the newly developed Gdansk Wound QoL scale. This scale was collaboratively developed by dermatologists, general and plastic surgeons, and wound care nurses with the goal of offering a comprehensive approach to assessing the QoL of both patients and their caregivers. It enables continuous monitoring of treatment outcomes and facilitates longitudinal comparisons. Furthermore, the scale aims to investigate the impact of the patient-physician relationship on the QoL of individuals with chronic ulcers. The primary objective of this pilot study was to take the initial steps towards validating this tool, while the secondary objective was to compare results following one month of holistic care.

Methods

The study participants were randomly selected individuals who had not previously sought treatment at the tertiary referral hospital in Poland, where the research was conducted.

The Gdansk Wound-QoL scale and a feasibility questionnaire were administered to patients with venous ulcers, as this group represents the largest cohort at our clinic requiring regular follow-ups and extensive wound management plans. Other patients with atypical wounds were excluded from the study, as some of these wounds may heal within one month, making comparisons with venous ulcers difficult. While this approach may introduce a selection bias, it also ensures uniform inclusion criteria for comparison purposes. Venous ulcers were diagnosed based on clinical examination, ankle-brachial index, and Doppler ultrasound. Prior to the study, patients were briefed on the research objectives and procedures, and given the opportunity to seek clarification from physicians if any terms were unclear. However, they completed the questionnaires anonymously without the supervision of healthcare professionals. Participation in the study was voluntary, and all participants provided informed consent for the use of their data for educational and commercial purposes, with the right to withdraw from the study at any time.

Patients were administered the Gdansk Wound QoL questionnaire on day 0 of the study and again on day 30. Subsequently, during follow-up visits, the same individuals provided feedback using a slightly modified questionnaire. Data collected from interviews and treatment outcomes during follow-up examinations were securely recorded in a database. Each patient was assigned a unique identifier, and randomization of patients was determined based on the order of application. Patient data were encrypted to comply with the Personal Data Protection Act. The study received approval from the Independent Bioethics Commission for Research at the Medical University of Gdansk (Bioethics Commission Agreement nr NKBBN/601/2019).

The questionnaire comprised 17 questions at the outset and 18 questions during follow-up, covering symptoms, embarrassment, mobility, social life, and work. Patients received specialized treatment and education. They evaluated their quality of life using the Numeric Rating Scale (NRS), where they rated pain from 0 (no pain) to 10 (worst pain) and responded to 7 questions regarding how the chronic wound impacted their quality of life. Responses were scored as follows: 0 – not at all, 1 – a little, 2 – moderately, 3 – severely.

The questionnaire assessed the severity of pain, the severity of odor, discomfort, impact on mobility, influence on social life and interactions with partners/friends, impact on work, and effect on the use of public transport. Patients were familiarized with the TIMERS guidelines, and physicians thoroughly explained wound management principles and the most suitable treatment for each patient. Patients were encouraged to contact the physician with further questions. Dressing changes, debridement, and dressings were individually tailored to each patient needs based on the guidelines.

Dressing change was conducted once a week at the clinic, and if more changes were needed, they were conducted by patients themselves or their family/caregivers. Regular follow-ups were conducted weekly over a one-month period.

Following the QoL questions, participants were asked to respond to additional inquiries before the commencement of the study:

“Did you know beforehand about the possibility of using compression therapy (compression stockings)?”, “Did you know beforehand about the possibility of using specialized dressings?”, “Did the presence of an ulcer restrict your access to health care?”, “Have you been denied admission to hospital because of the ulcer?”.

During follow-up, patients were presented with additional questions pertaining to healthcare relations. These included inquiries such as, “Do you feel that your knowledge about the disease has increased?”, “Does the awareness of the possibility of receiving help (contact with a doctor) make you feel better?”, “Do you think that the therapy recommended in the clinic is effective?”, “Do you fulfill all the recommendations received in the clinic?”, “Did you increase your activity after hospitalization?”, “Were you satisfied with the course of treatment proposed by the current doctor?”, “Do you feel that the current doctor is particularly involved in the treatment?”

To avoid bias in this study, only patients who had never had contact with the clinic or its physicians were recruited in the study.

Statistical Analysis

Statistical analyses were performed with SPSS Statistics version 25 (IBM®). The Gdansk Wound QoL scores were calculated by calculating percentage of patients that answered questions. Internal correlation between time was also compared statistically using Cronbach alpha coefficient, where score 0.7 is considered acceptable and score over 0.9 is good. As the result did not show normal distribution with Shapiro-Wilk test, non-parametric Spearman correlation was calculated and is large when $r = 0.5$ and small when $r = 0.1$.

Results

One hundred eight patients (61.1% women) participated in the study. Mean age was 76.1 ± 10.8 years, where all patients had venous ulcers of average area 10.8 cm^2 . All the participants enrolled completed the study and showed up on all follow-ups to change the dressing, as well as the last follow-up after 30 days and completed the questionnaire. Response rate at both times was 100%. All patients asked, agreed to participate.

Study group characteristics are presented in Table 1, and it illustrates that 66 patients had a positive anamnesis for

Table 1. Sociodemographic Characteristics of 108 Patients With Chronic Ulcers

Variables		N
Sex		
	Male	42
	Female	66
Previously treated ulcer		
	Yes	66
	No	42
Swollen legs		
	Yes	84
	No	24
Erythema at the wound site		
	Yes	84
	No	24
Pain (Numeric Rating Scale)		
	0-5	42
	6-10	66
How old is the ulcer?		
	Months	12
	Years	96
Uni- or bilateral		
	Unilateral	90
	Bilateral	18
Ulcer area		
	>30 cm ²	30
	15-30 cm ²	0
	5-15 cm ²	30
	Up to 5 cm ²	42

previously healed leg ulcer 96 patients have had their contemporary ulcer for years, and 96 patients had yellow exudate and 36 patients had an intensive abundance of it. Furthermore, 30 patients had an ulcer area bigger than 30 cm² and 18 patients had bilateral ulcers at the time of the study.

Only 16.7% of the study group knew beforehand about the possibility of using compression therapy (compression stockings) and 38.9% knew about the possibility of using specialized dressings. Surprisingly 22.2% of the patients have been previously denied admission to hospital because of the ulcer and 33.3% have had restricted access to health care due to presence of an ulcer.

The HRQoL was calculated by summing the score of each question resulting in a maximum of 21 and minimum of 0, both on day 0 and day 30. On average HRQoL was 8.3 on day 0 and 6.1 on day 30. The improvement of quality of life was noticed in 67.7% of patients and it was statistically significant ($P = 0.0001$). On average, quality of life increased by 36.7% after 30 days trial.

Almost 61.1% of patients noticed reduction in pain ($P = 0.0001$) and no one stated deterioration in pain (Figure 1). 33.3% of the patients reported improvement in intensity of smell ($P = 0.003$), and 0.009% (one person) reported deterioration in odor. 38.9% of the patients reported improvement in walking ($P = 0.002$). 38.89% of participants felt generally less embarrassed after 30 days and 50% noticed improvement in social life ($P = 0.001$). Of 18 patient who have been working at the time being, 6 has claimed improvement in comfort at work, 16.7% stated improvement in discomfort during travel with public transportation. 18 participants noticed improvement in the contact with their partner, yet 12 claimed worsening in this sphere of life.

Moreover, on the follow up visit 94.4% of the patients stated that their knowledge on the disease has increased and everyone was satisfied with the course of treatment proposed by the current doctor. All the participants claimed that they feel that the current doctor is particularly involved in the treatment and the awareness of the possibility of receiving help (contact with a doctor) made them feel better. Only 12 patients felt that the therapy recommended in the clinic was not effective, one of whom also admitted that he/she was the only one who did not fulfil all the recommendations received in the clinic. Furthermore, 44.4% of the study group increased their activity at the end of the study.

The internal consistency of Gdansk Wound-QoL was high on both day 0 ($\alpha = 0.779$) and day 30 ($\alpha = 0.829$), and the value was highest for contact with partner ($\alpha = 0.925$) and social life ($\alpha = 0.856$). Retest-reliability ($r = 0.85$, $P = 0.001$) and convergent validity with DLQI ($r = 0.75$, $P = 0.001$) were sufficient.

Conclusions

The study findings indicated that most participants expressed satisfaction with the follow-up and care they received during the study period. Many patients reported encountering challenges such as poor communication and unclear recommendations from previous healthcare providers, which contributed to a lack of trust in other healthcare facilities where they did not have an assigned physician. Patients with chronic leg ulcers often face difficulties in securing hospitalizations, particularly for surgical procedures, due to their overall health status and heightened risk for post-operative infections. However, the long-term prognosis for these patients may not necessarily be worse than those without leg ulcers, but there is a clear need for enhanced education and training in wound care among healthcare personnel.

All participants found the questionnaire to be user-friendly, easy to understand, and not burdensome to complete.

Existing studies have demonstrated the significant impact of chronic wounds on patients QoL. Established scales

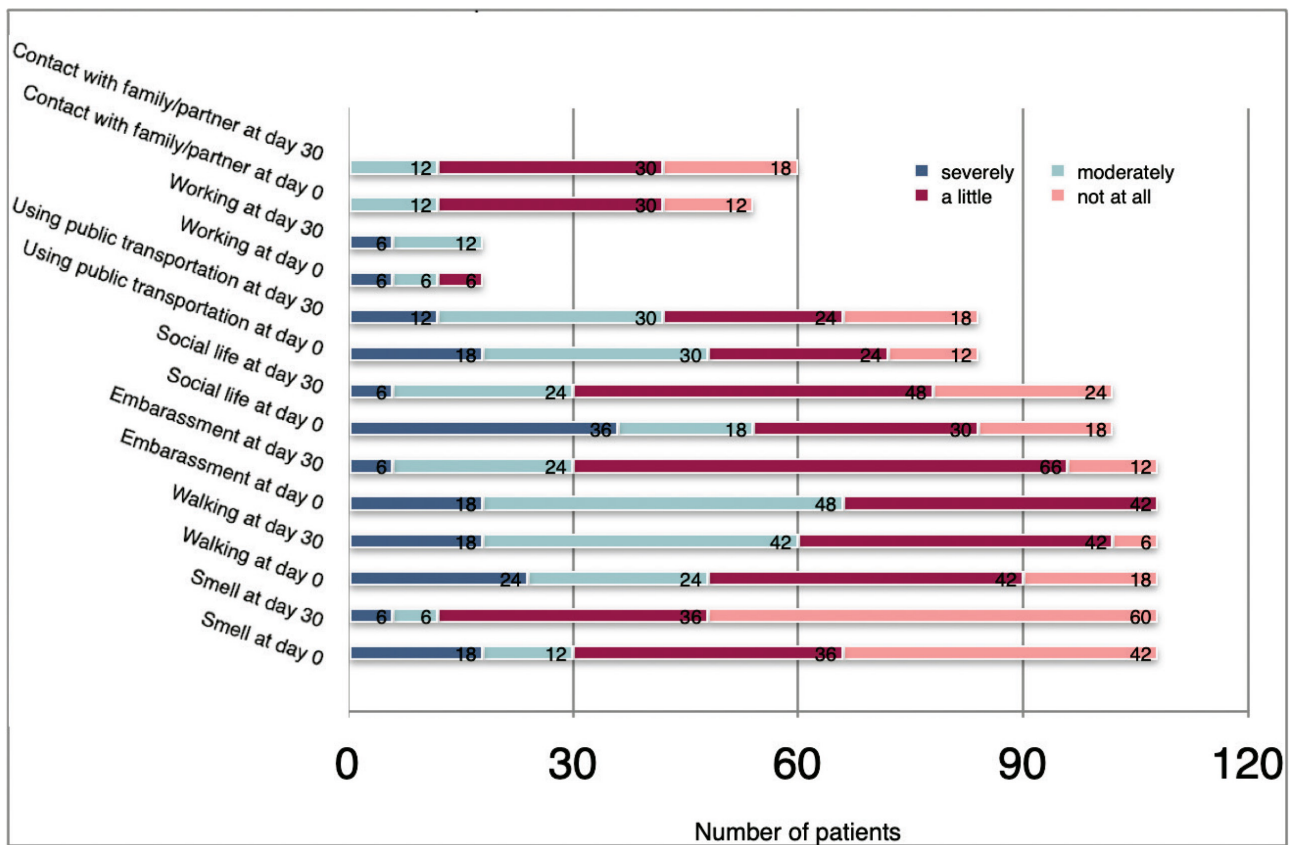


Figure 1. “How much did the chronic affect your quality of life?”

such as the Freiburg Life Quality Assessment for wounds (FLQA-w), Cardiff Wound Impact Schedule (CWIS), and Würzburg Wound Score (WWS) are widely used for QoL assessment, although they are lengthy, ranging from 4 to 7 pages and containing 47 questions [9,10]. In contrast, the Gdansk Wound-QoL scale comprises 17 questions on a single page. Notably, these established scales lack inquiries about the quality of care and the patient-physician relationship.

The uniqueness of the Gdansk Wound-QoL scale lies in its recognition of the pivotal role played by the physician-patient relationship. It offers an unbiased method to measure this relationship, acknowledging its significant impact on patients QoL. Patient-centered care, as advocated by the NHS UK, emphasizes understanding patients as individuals with distinct needs, fears, and expectations [11]. Collaboration between physicians and patients is highly recommended, and patients expect clear, jargon-free information about their condition and potential treatments.

Several patients, however, stated poorer contact with family members or partner. Possible explanation for this phenomenon is that patients become more involved in wound care, than personal relations and assume that partners or family members experience lack of interest or interaction.

The study results indicated that patients value the ability to contact their physician for additional information or assistance in case of adverse effects or sudden deterioration

in their condition. Establishing trust between patients and their physicians is vital. Providing patients with contact details enhances their confidence in the physician, fostering proper compliance, which is crucial for achieving common treatment goals [12,13].

Many physicians tend to overlook the aspect of wound palliation and often fail to inquire about patients expectations and the aspects of their condition causing the most distress [14]. Acknowledging that patients live with the disease around the clock is essential. Patients deserve transparent insights into their condition and unbiased information about the advantages and disadvantages of various treatment methods. This approach facilitates an active dialogue, enabling patients to participate directly in their therapeutic plans. Such involvement instills confidence and trust in the physician, ensuring proper compliance and alignment with the treatment goals.

The study limitations include a small sample size from a single center, which may restrict the generalizability of the findings. To enhance the applicability and robustness of the Gdansk Wound-QoL scale, conducting a multicenter trial involving diverse environments and cultures is recommended. External validation through collaboration among multiple centers would yield more comprehensive results, leveraging resources, enlarging the sample size, and fostering the exchange of knowledge and experiences across a network.

Additionally, broadening the study group to include patients with various types of leg ulcers would validate the tool for all individuals with such conditions.

Furthermore, the 1-month follow-up period is relatively short for assessing treatment outcomes comprehensively. Future research should focus on longer follow-up periods, as wound care typically constitutes a prolonged journey. Evaluating patients' satisfaction with treatment and the patient-physician relationship over several months would enable the identification of potential differences. We anticipate that our preliminary findings will facilitate collaboration with partners for the validation of this novel assessment tool in our future endeavors.

In conclusion, the Gdansk Wound-QoL scale presents wound care professionals with a valuable instrument for gaining comprehensive insights into the health-related QoL of individual patients. Its practical utilization in routine medical practice has the potential to enhance the precision of both clinical interventions and research endeavors. By furnishing clinicians with well-structured feedback on treatment outcomes, this tool holds promise for reducing wound healing durations and consequently diminishing the overall costs of treatment, while simultaneously alleviating patient distress. It is important to note that this study serves as a pilot investigation, representing the initial phase in the validation process of the tool, necessitating further research for comprehensive validation.

Moreover, the study underscores the importance of fostering a professional and empathetic physician-patient relationship, complemented by thorough patient education. Cultivating such relationships and ensuring patients receive adequate education are essential steps toward improving the overall QoL for individuals grappling with chronic wounds.

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