



Validity and feasibility of the wound-QoL questionnaire on health-related quality of life in chronic wounds

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Manuscript received: June 9, 2017
Accepted in final form: August 19, 2017

DOI:10.1111/wrr.12583

ABSTRACT

Chronic wounds have a major socioeconomic impact due to their frequency, chronicity, and societal costs. Patients experience substantial quality of life (QoL) impairments. The use of questionnaires for a continuous assessment of QoL and resulting interventions to improve the situation of the individual are an important cornerstone of a guideline-based wound care. The aim of this study was to investigate the validity of the Wound-QoL questionnaire. Patients with chronic wounds from two different centers were included in the prospective study. All patients completed the Wound-QoL and two other QoL questionnaires (European Quality of Life-5 Dimensions, EQ-5D, and Freiburg Life Quality Assessment for wounds, FLQA-wk) at baseline and at two more time points (4 and 8 weeks, respectively). Wound status was defined with an anchor question. Two hundred and twenty-seven patients (48.5% women) participated in the study. Mean age was 66.9 years (range 17–96, median 69.5). Indications were venous leg ulcers (40.1%), pyoderma gangraenosum (14.1%), diabetic or ischemic foot ulcers (5.3%), pressure ulcers (2.6%), and other etiologies (30.0%). The Wound-QoL showed good internal consistency, with high Cronbach's alpha in all the subscales and in the global scale in all time points (>0.8). Convergent validity was satisfactory since there were significantly ($p \leq 0.001$) good correlations with the EQ-5D (range = 0.5–0.7) and FLQA-wk global score ($r > 0.8$) at every time point. Responsiveness was high, too. The Wound-QoL is a simple, valid tool for the longitudinal assessment of QoL in patients with chronic wounds. This questionnaire is suitable for use in clinical trials, quality of care studies and clinical routine.

Chronic wounds have a major socioeconomic impact due to their frequency, chronicity, and societal costs. Those affected are of higher age, their disease is often lasting for years and is furthermore recurrent and often accompanied by multiple comorbidities.^{1,2} Wounds are associated with pain, discharge, odor, and limited mobility. Patients often need professional care for years. Therefore, chronic wounds are associated with major restrictions of quality of life. This reduction of health-related quality of life (HRQoL) and its improvement subsequent to healing has been quantified in several studies.^{3–8}

Treatment by specialized wound professionals or clinics is positively associated with HRQoL.^{3,9–11} This could be shown for a guideline-based wound management as well, although Franks et al. found that the positive effect of a change of wound care management diminishes over a protracted observation period. This could be explained by the number and severity of comorbidities in this patient population and the method of assessment of HRQoL, which was not specific for the actual disease.⁵ The advantage of

disease-specific instruments lies in the precise evaluation of burdens that mainly apply to those affected by the particular illness, but not for the sick in general.

HRQoL reflects the personal health condition of an individual in physical, social, emotional, and functional dimensions. It is necessary to evaluate the well-being of patients in the aforementioned dimensions. The assessment of HRQoL is multidimensional and cannot be differentially evaluated with a single scale only. In recent years, a number of instruments assessing HRQoL were developed and validated. Mainly three instruments are currently being used in Germany, the Würzburg Wundscore, the Cardiff Wound Impact Schedule, and the Freiburg Life Quality Assessment for wounds.^{12–14} Although these widely used questionnaires focus on various spheres of life and disease-specific impairments, their length may reduce willingness to use in daily practice. The continuous assessment of HRQoL and resulting interventions to improve the situation of the individual are an important cornerstone of a guideline-based wound care.

Wound-QoL questionnaire on quality of life with chronic wounds

With the following questions, we aim to find out how your chronic wound(s) affect(s) your quality of life.

Please tick one box per line!

In the last seven days ...		not at all	a little	moderately	quite a lot	very much
1	...my wound hurt	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2	...my wound had a bad smell	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3	...there was a disturbing discharge from the wound	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4	...the wound has affected my sleep	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5	...the treatment of the wound has been a burden to me	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6	...the wound has made me unhappy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7	...I have felt frustrated because the wound is taking so long to heal	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8	...I have worried about my wound	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9	...I have been afraid of the wound getting worse or of new wounds appearing	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10	...I have been afraid of knocking the wound	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11	...I have had trouble moving about because of the wound	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12	...climbing stairs has been difficult because of the wound	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13	...I have had trouble with day-to-day activities because of the wound	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14	...the wound has limited my leisure activities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15	...the wound has forced me to limit my activities with others	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16	...I have felt dependent on help from others because of the wound	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
17	...the wound has been a financial burden to me	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Figure 1. The final Wound-QoL questionnaire (UK English version: translated from the original German version).

"Wound-QoL" questionnaire on Health-related Quality of Life in Chronic Wounds • Augustin et al. 2014; Blome et al. 2014

A short and easy-to-use questionnaire, the Wound-QoL (Figure 1), has been recently developed and a virtual validation study has been published.¹⁵ The aim of the present study is to measure validity of this tool in a longitudinal design under routine care conditions.

MATERIALS AND METHODS

Patients and treatment

This longitudinal validation study of the Wound-QoL consisted of the application of HRQoL instruments in chronic wound patients in two large specialized wound centers (University Medical Center Hamburg-Eppendorf, Germany and a Wound Care Clinic in Marburg, Germany) and four community based practices.

Adult patients (age ≥ 18 years) with an existing chronic wound by definition were included at any chosen time point within the therapeutic programme. Patients with a lack of mental, physical, or linguistic ability were excluded. Written consent was provided and written data protection policy was available.

Each patient was asked to fill in the Wound-QoL and the Freiburg Life Quality Assessment for wounds (FLQA-wk) in a random order at three time points (T1: day 0, T2: week 4–6, T3: week 8–10) as well as the generic HRQoL instruments EQ-5D-3L and EQ VAS.^{16,17} The FLQA-wk aims to measure the impairment of HRQoL of people with chronic wounds over the previous week. It is made up of 24 items, distributed in six domains: physical symptoms, daily life, social life, psychological wellbeing, treatment and satisfaction. Scores range from 0 (no impairment) to 5 (highest

impairment). The EQ-5D-3L questionnaire measures current health state covering five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) and the EuroQol visual analog scale (EQ VAS) ranges from 0 = worst imaginable to 100 = best imaginable health.

Wound status was updated in each time point with an anchor question reflecting patients' global rating of change in a Likert scale (1 = much better, 5 = much worse). The wound size was calculated as $(\text{length}/2) * (\text{width}/2)$.

Epithelization was used as a marker for wound improvement and was assessed in the following categories: none, up to 25%, up to 50%, up to 75%, up to 100%. A wound was defined as healed if epithelization was up to 100%.

The following parameters were tested to determine longitudinal validity and other measurement properties:

- (1) Number of missing values.
- (2) Floor and ceiling effects: Amount of people with the lowest and highest global score.
- (3) Change in the mean total score from T1 to T2 and from T1 to T3.
- (4) Internal consistency: Cronbach's alpha.
- (5) Item selectivity: Spearman correlation of single items and subscale with global score.
- (6) Convergent validity: Spearman correlation of the Wound-QoL with further HRQoL instruments and their subscales.
- (7) Responsiveness: Spearman correlation of the change in the total score from T1 to T2 with the change in the score of the other applied HRQoL questionnaires (correlation of T2 values). The same procedure was applied for the change from T1 to T3. Clinical responsiveness (correlation with the change of a clinical criterion) was tested with an anchor question reflecting patient's global rating of change.

RESULTS

Patients

In total, $n = 227$ patients were included from March 2014 to March 2016. Age of the study population ranged from 18 to 96 years (mean age 66.9 ± 12.7 , median 69.5). 51.5% participants were male, 48.5% female. Wound etiology was variable (Table 1) and included leg ulcers ($n = 123$, 54.2%; including $n = 91$ of vascular origin and $n = 32$ due to pyoderma gangraenosum), diabetic or ischemic foot ulcers ($n = 12$, 5.3%), pressure ulcers ($n = 6$, 2.6%), as well as other wounds ($n = 68$, 30%). Mean wound size decreased from 8.1 cm^2 at T1 to 7.8 cm^2 at T2 and 7.1 cm^2 at T3. The percentage change from T1 to T2 was -7.0% and from T1 to T3 -16.8% . The percentage of patients with a healed wound (epithelization up to 100%) was 3.8% at T2 and 15.2% at T3.

Number of missing values

Participation varied over time ($n_{T1} = 227$, $n_{T2} = 209$, $n_{T3} = 202$). The Wound-QoL global score could not be calculated from questionnaires with more than 4 missing

Table 1. Demographic and clinical characteristics of the study participants at baseline

	<i>n</i>	Mean \pm SD
Age (years)	227	66.9 ± 12.7
Duration of wound persistence (months)	221	25.9 ± 66.1
	<i>n</i>	%
Sex		
Male	110	48.5
Female	117	51.5
School education degree		
Did not graduate	2	0.9
General education (9 years)	88	38.8
Middle school (10 years)	69	30.4
Higher education (12 or 13 years)	52	22.9
Other	13	5.7
Missing	3	1.3
Employment		
Employed	56	24.7
Not employed	170	74.9
N.a.	1	0.4
Wound etiology		
Leg ulcers	123	54.2
Diabetic or ischemic foot ulcers	12	5.3
Pressure ulcers	6	2.6
Other (arterial, surgical, traumatic, malignant wounds, burns)	68	30.0
Missing	18	7.9
Total	227	100

items and they were not considered in the study results ($n_{T1} = 6$, $n_{T2} = 20$, $n_{T3} = 25$). The item with the highest number of missing values in all time points was "climbing stairs has been difficult because of the wound," and regarding subscales, the "Wound-QoL subscale everyday life."

Floor and ceiling effects

A low floor effect was observed in T1: 0.5%, T2: 1%, and T3: 4%. Ceiling effects were also low (0%, 1%, 0.5%, respectively).

Change in the mean total score from T1 to T2 and from T1 to T3

The mean value of the Wound-QoL global score decreased over time (T1: 1.89 ± 0.95 , T2: 1.50 ± 0.91 , T3: 1.27 ± 0.93). T-test showed significance of change for T1/T2 difference and T1/T3 differences ($p \leq 0.001$).

Responsiveness

A high correlation was found for the change (absolute difference) in the Wound-QoL global score with change in

Table 2. Correlation of change in Wound-QoL with change in FLQA-wk, anchor question (subjective wound status compared to before treatment) and wound improvement (percentage change of wound size) from baseline to first (T2; 4–6 weeks) and baseline to second (T3; 8–10 weeks) follow-up (*r* = correlation coefficient; *p* = significance level; *n* = number of patients)

		Change in Wound-QoL global score	
		T1 to T2	T1 to T3
Change in FLQA-wk	<i>r</i>	0.609	0.679
	<i>P</i>	≤0.001	≤0.001
	<i>n</i>	199	194
Anchor question	<i>r</i>	−0.433	−0.358
	<i>p</i>	≤0.001	≤0.001
	<i>n</i>	189	188
Wound improvement	<i>r</i>	0.336	0.356
	<i>p</i>	≤0.001	≤0.001
	<i>n</i>	186	184

the FLQA-wk. Moderate correlation was found with the clinical anchor question (wound status as compared to before treatment) and wound improvement (percentage

Table 3. Wound-QoL validity (correlation with convergent instruments; *r* = correlation coefficient; *p* = probability of error; *n* = number of patients).

		T1	T2	T3
		baseline	4–6 weeks	8–10 weeks
Wound-QoL global score/FLQA-wk global score	<i>r</i>	0.820	0.854	0.890
	<i>p</i>	≤0.001	≤0.001	≤0.001
	<i>n</i>	220	204	198
Wound-QoL global score/EQ-5D-3L Score	<i>r</i>	−0.565	−0.487	−0.721
	<i>p</i>	≤0.001	≤0.001	≤0.001
	<i>n</i>	212	196	195
Wound-QoL global score/EQ VAS	<i>r</i>	−0.342	−0.465	−0.530
	<i>p</i>	≤0.001	≤0.001	≤0.001
	<i>n</i>	216	201	196
Wound-QoL global score/Limited by the wound (Anchor question)	<i>r</i>	0.795	0.703	0.718
	<i>p</i>	≤0.001	≤0.001	≤0.001
	<i>n</i>	206	198	195
Subscale “everyday life”: Wound-QoL/FLQA-wk	<i>r</i>	0.864	0.835	0.898
	<i>p</i>	≤0.001	≤0.001	≤0.001
	<i>n</i>	219	201	198
Subscale “body”/“physical ailments”: Wound-QoL/FLQA-wk	<i>r</i>	0.824	0.833	0.892
	<i>p</i>	≤0.001	≤0.001	≤0.001
	<i>n</i>	218	203	199
Subscale “psychological well-being”: Wound-QoL/FLQA-wk	<i>r</i>	0.687	0.674	0.759
	<i>p</i>	≤0.001	≤0.001	≤0.001
	<i>n</i>	221	206	198

change of wound size) (Table 2). The correlation of the change in Wound-QoL subscales with the change in FLQA-wk subscales was also highly significant, ranging from *r* = 0.514 (psyche) to *r* = 0.661 (body) for T1-T2 and from *r* = 0.577 (psyche) to *r* = 0.698 (body) for T1-T3.

The Wound-QoL global score was significantly better among those with a healed wound compared to the others both at T2 (0.5 vs. 1.6; *p* = 0.002) and T3 (0.7 vs. 1.4; *p* ≤ 0.001). The same holds true for the change in the global score.

Internal consistency

Internal consistency was high in the three time points (T1: Cronbach’s alpha = 0.928, *n* = 203; T2: Cronbach’s alpha = 0.937, *n* = 184; T3: Cronbach’s alpha = 0.947, *n* = 181).

Correlation of subscales with global score

Spearman correlation of the total value of each of the three subscale scores (body, psyche and everyday life) and Wound-QoL global score was superior to 0.8 in all three time points (T1, T2, and T3), ≤ 0.001.

Item selectivity of the 17 items

Item selectivity ranges were very similar over time. In T1, item selectivity ranged from 0.358 to 0.834; T2: 0.441 to 0.821, and T3: 0.538 to 0.828.

Convergent validity

Correlation between FLQA-wk and Wound-QoL was high for both global score and subscales (Table 3). This was observed in all three time points (higher than $0.8 \leq 0.001$ in the subscales on physical ailments and everyday life). Correlations with the other HRQoL instruments were significant in all three time points: EQ-5D (r range = -0.49 to -0.72) and EQ-5D VAS (r range = -0.34 to -0.53).

DISCUSSION

Measuring HRQoL in patients with chronic wounds is a cornerstone of evidence-based wound treatment. Within the limitations of measuring a complex, multidimensional and very individual construct like HRQoL, standardized questionnaires have been shown to be useful in clinical care as well as in research.¹⁸

There is a need for validated, easy-to-use instruments leading to reproducible, sensitive and feasible information from the patient perspective. Moreover, the widespread use of these instruments would be desirable in order to make data comparable.

The Wound-QoL, a one-page questionnaire, has been developed to meet those needs.¹⁹ It has been conceptualized on the basis of existing instruments, whose contents were condensed to the most necessary. The results of the virtual validation using data of the longitudinal study on the preexisting HRQoL instruments indicated validity, internal consistency, and responsiveness.¹⁵ A limitation of the methodology of development of the Wound-QoL can be seen in the virtual validation, whose results can only serve as an estimation of the true psychometric properties of the Wound-QoL. For this reason the current longitudinal validation study has been conducted.

Internal validity, criterion validity and convergent validity were high in the three time points. Item selectivity was preserved over time. Good responsiveness was found over time regarding change in both generic and disease-specific HRQoL.

As a statistically significant change in a PRO (patient-reported outcomes) score does not necessarily represent a clinically important improvement, and as it can be difficult to know if a PRO score is acceptable from the patient's point of view, Revicki et al.²⁰ recommend 0.3–0.35 as a correlation threshold to define an acceptable association between an anchor and a PRO change score. Consequently, in our study, since the correlation between wound status in T2 compared with before treatments and Wound-QoL global score difference T1/T2 is -0.433 and T1/T3 is -0.358 we can consider it both a statistically and clinically relevant improvement.

As a limitation, the current data were derived from specialized centers with a high expertise in wound care. There may thus be a selection of hard-to-heal wounds. Nevertheless, the study included patients from hospitals as well as from office-based physicians and a large variety of indications, thus providing a certain level of variability.

In conclusion, the newly developed Wound-QoL was found to be valid and responsive and is useful as a short instrument for assessing health-related quality of life.

ACKNOWLEDGMENTS

Source of Funding: No external funding was provided to this study.

Conflicts of Interest: The authors declare no conflict of interest.

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