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Validation of the Wound-QoL-17 and the Wound-QoL-14 in a European sample of 305 patients with chronic wounds

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Abstract

The Wound-QoL assesses the impact of chronic wounds on patients' health-related quality of life (HRQoL). A 17-item and a shortened 14-item version are available. The Wound-QoL-17 has been validated for multiple languages. For the Wound-QoL-14, psychometric properties beyond internal consistency were lacking. We aimed to validate both Wound-QoL versions for international samples representing a broad range of European countries, including countries for which validation data had yet been pending. Patients with chronic wounds of any aetiology or location were recruited in Austria, Lithuania, the Netherlands, Poland, Slovakia, Spain, Switzerland and Ukraine. Psychometric properties were determined for both Wound-QoL versions for the overall sample and, if feasible, country-wise. We included 305 patients (age 68.5 years; 52.8% males). Internal consistency was high in both Wound-QoL-17 (Cronbach's α: 0.820–0.933) and Wound-QoL-14 (0.779–0.925). Test–retest reliability was moderate to good (intraclass correlation coefficient: 0.618–0.808). For Wound-QoL-17 and Wound-QoL-14, convergent validity analyses showed highest correlations with global

HRQoL rating ($r = 0.765$; $r = 0.751$) and DLQI total score ($r = 0.684$; $r = 0.681$). Regarding clinical data, correlations were largest with odour ($r = -0.371$; $r = -0.388$) and wound size ($r = 0.381$; $r = 0.383$). Country-wise results were similar. Both Wound-QoL versions are valid to assess HRQoL of patients with chronic wounds. Due to its psychometric properties and brevity, the Wound-QoL-14 might be preferrable in clinical practice where time is rare. The availability of various language versions allows for the use of this questionnaire in international studies and in clinical practice when foreign language patients are being treated.

KEYWORDS

outcomes research, quality of life, ulcer

Key Messages

- Chronic wounds largely impact on patients' health-related quality of life. The Wound-QoL-17 and Wound-QoL-14 are frequently used to assess health-related quality of life in these patients with chronic wounds.
- The aim of this study was to validate both Wound-QoL versions for international samples representing a broad range of European countries, including countries for which validation data had yet been pending.
- The results show favourable psychometric properties for both Wound-QoL-17 and Wound-QoL-14.
- The availability of various language versions allows for the use of this questionnaire in international studies and in clinical practice when foreign language patients are being treated.

1 | INTRODUCTION

Chronic wounds are characterised by insufficient healing in a timely manner[1] and/or by being caused by an underlying condition.[2,3] A systematic review revealed a total prevalence of chronic wounds 1.67 per 1000 people.[4] Prevalence rates are higher in people above the age of 65 years,[5] which presents a challenge particularly in the European ageing society. In addition to the economic burden of chronic wounds on societal level,[5] treatment is often complex and time-consuming for the individual patient[6] and burdensome for caregivers.[7,8] Many patients are strained by long-lasting comorbidity[9] and marked loss of health-related quality of life (HRQoL).[5]

Patients experience HRQoL impairments on various levels: Besides physical wound-specific burden, such as exudate, odour and wound pain, the condition can cause psychological strain, which can lead to sleep disturbances, anxiety and depression.[10] Living with chronic wounds can impact the financial status of patients[11] and cause considerable restrictions in everyday activities[11] as well as social participation.[12]

To assess the impact of chronic wounds on all these dimensions, wound-specific HRQoL questionnaires can be used. They allow for treatment planning, evaluation and patient–physician communication. To increase feasibility in both routine care and research, these questionnaires need to be short and easy to use.

Therefore, we have developed the Wound-QoL questionnaire; currently, two versions are available. The original Wound-QoL with 17 items (Wound-QoL-17) was established in 2014.[11] Recently, a shortened 14-item version (Wound-QoL-14) was developed, in which three items of the Wound-QoL-17 are omitted due to statistical and contextual considerations.[13] In both versions, items are answered on a 5-point Likert scale ranging from 'not at all' to 'very'. From these, a global score and three subscale scores (body, psyche, everyday life) can be calculated (mean scores; range: 0–4). The subscales are calculated from five (body, psyche) to six (everyday life) items in the Wound-QoL-17 and from four (body, psyche) to five (everyday life) items in the Wound-QoL-14. In each version, one item is not used for subscale calculation (Wound-QoL-17: item on financial burden; Wound-QoL-14: item on treatment burden).

Both Wound-QoL versions are available in numerous languages. For several languages, validation data of the Wound-QoL-17 exist.[11,14–22] For the Wound-QoL-14, we could confirm internal consistency and cross-cultural metric invariance[13]; the analysis of further psychometric properties was still lacking.

With the current study, we aim to provide validation data for both Wound-QoL versions for international samples representing a broad range of European countries, including a range of countries for which validation data had been lacking, yet.

2 | METHODS

2.1 | Ethics

The local Ethics Committee of the Medical Association of Hamburg (Ethikkommission der Ärztekammer Hamburg) approved this study in June 2019 (PV7029). Secondary ethic votes were obtained from local ethic committees in the participating countries.

2.2 | Participants

This study aimed to enrol patients with chronic wounds treated in outpatient dermatological clinics in 10 European countries. Two project partners (France, Italy) were not able to continue participation prior to start of recruitment, resulting in eight participating countries (Austria, Lithuania, the Netherlands, Poland, Slovakia, Spain, Switzerland, Ukraine). Each study centre aimed at recruiting 50 patients. Inclusion criteria were a minimum age of 18 years, diagnosis of chronic wound(s) and ability to understand and complete the questionnaire.

2.3 | Procedure

Patients with chronic wounds were recruited during their regular visit in one of the participating study centres. Participants received written information, and informed consent was obtained. They completed a paper-based questionnaire including questions on sociodemographic characteristics, questions on wound characteristics and patient-reported outcome measurements (PROMs). Additionally, participants received the Wound-QoL as stand-alone questionnaire and were instructed to complete this questionnaire 7 days after their visit. Healthcare professionals completed the clinical questionnaire assessing wound characteristics.

2.4 | Measures

Patients answered the following PROMs:

- Wound-QoL (patients completed the 17-item version; from this, we also calculated the 14 version).
- Dermatology Life Quality Index (DLQI[23]) on dermatology-specific HRQoL: 10 items; 4-point Likert scale; global scale range: 0–30; subscales: symptoms and feeling, daily activities, leisure subscale, work and school, personal relationships, treatment (range: either 0–3 or 0–6).
- EQ-5D-5L[24] on generic HRQoL: 5 items; five-level response options; country-specific value sets; for the present study, value sets from two participating countries were used representing Central/Eastern and Western European countries: Poland (range: −0.590–1[25]) and Spain (range: −0.501–1[26]).
- EQ VAS on subjective health: one-page numeric visual analogue scale; range: 0–100.
- Global rating on HRQoL: single item; 5-point Likert scale; range: 1–5.
- Numeric rating scale (NRS) on pain at dressing change: single item; 11-point rating scale; range: 0–10.
- NRS on pain at rest: single item; 11-point rating scale; range: 0–10.

Wound type and duration (in months) were assessed in both patient and clinical questionnaires.

The clinical questionnaire assessed the following wound characteristics:

- Wound slough (multiple choice [MC]): none, necrosis, fibrin; in analyses none vs. present).
- Wound edge (MC): not irritated, flushed/reddened, oedematous, macerated, livid, necrotic, hyperkeratotic, undermined; in analyses: not irritated vs. irritated).
- Wound environment (MC: not irritated, reddened, oedematous, macerated, moist, scaly/flaky, erosive; in analyses: not irritated vs. irritated).
- Odour (none, present).
- Amount of exudate (none, little, medium, severe).
- Wound size (in cm^2).

2.5 | Statistical analysis

Sample characteristics and distribution of the questionnaire items and scores were analysed using descriptive statistics, depending on the scale level. For validation analysis, we calculated for global and subscale scores of Wound-QoL-17 and Wound-QoL-14: floor and ceiling effect (percentage of patients with lowest and highest possible score); internal consistency (Cronbach's α); item selectivity (correlation of global score with items and subscale scores and correlation of subscale scores with items; Spearman correlation); convergent validity (correlation of global and subscale scores with other

measurements; Spearman correlation for continuous, Mann–Whitney *U* test for dichotomous or Kruskal–Wallis test for ordinal variables); and test–retest reliability (intraclass correlation [ICC]; two-way mixed, absolute agreement; when retest was completed 5–9 days later). For convergent validity testing, hypotheses were developed prior to analysis based on previously published data (Appendix S1).

Cronbach's α was considered good when between 0.70 and 0.95.[27] Effect sizes were considered small when $r > 0.10$ or $\eta^2 > 0.01$, medium when $r > 0.30$ or $\eta^2 > 0.06$ and large when $r > 0.50$ or $\eta^2 > 0.14$.[28] ICC was rated moderate when >0.50, good when ICC >0.75 and excellent when ICC >0.90.[29]

All analyses were conducted using SPSS v. 27.0 (IBM, Armonk, NY, USA). Analyses were conducted for the European sample and country-wise for those countries having collected data for at least $n = 30$ patients.

3 | RESULTS

In the following, results for the European sample are reported. Country-specific results are shortly reported at the end of this section and displayed in detail in the Appendix S1.

3.1 | Sample characteristics

The sample (Tables 1–4) consisted of 305 participants of which 221 (72.4%) sent back the retest questionnaire. Mean age was 68.5 years (SD: 13.9, range: 28–96), and 52.8% ($n = 161$) were male. As reported in the clinical questionnaire, the most frequent wound types were venous leg ulcers ($n = 101$, 33.1%), followed by diabetic foot ulcer ($n = 76$, 24.9%) and other wounds ($n = 75$, 24.6%; e.g. oncological wounds, post-surgical wounds, non-healing wound after amputation). Mean wound duration was 20.0 months (SD: 54.4, median: 6.0 range: 0–600).

3.2 | Number of missing values

Two patients (0.7%) did not fill in the Wound-QoL at all, whereas 273 (89.5%) did not have any missing value. The other patients had between one ($n = 18$, 5.9%) and six ($n = 1$, 0.3%) missing items (mean: 0.3; median: 0.0). Of those answering the Wound-QoL, between none (0.0%) and six (2.0%) patients had missing values per item. Descriptive characteristics of the Wound-QoL items and scales are displayed in Table 5.

Of the 221 patients with retest data, two did not complete the Wound-QoL (0.9%), whereas 196 (88.7%) completed all items. The other patients had between one ($n = 19$, 8.6%) and six ($n = 1$, 0.5%) missing items (mean: 0.3; median: 0.0). Of those answering the Wound-QoL, between none (0.0%) and six (2.8%) patients had missing values per item.

3.3 | Wound-QoL-17

3.3.1 | Floor and ceiling effects

In the everyday life subscale, 16 patients (5.3%) achieved the lowest possible score, indicating a small floor effect. In the other (sub)scales, no floor effect was detectable (three (1.0%) to 10 (3.3%) patients with lowest possible score).

In the global scale and the body subscale, no ceiling effect was detectable with three (1.0%) and 10 (3.3%) patients achieving the highest possible score, whereas the psyche ($n = 31$, 10.2%) and the everyday life subscale ($n = 27$, 8.9%) did show a ceiling effect.

3.3.2 | Internal consistency

Across all scales, internal consistency (Table 6) was high with Cronbach's α ranging from 0.933 (global scale, $n = 273$) to 0.820 (body subscale, $n = 289$).

3.3.3 | Item selectivity

Item selectivity (Appendix S1) ranged from $r = 0.524$ to $r = 0.821$ for the global score with highest correlation coefficients in items on everyday activities ($r = 0.821$), moving around ($r = 0.798$) and being unhappy ($r = 0.787$). The lowest correlation coefficients were detected for items on disturbing discharge from the wound ($r = 0.524$) and wound smell ($r = 0.535$). Subscale item selectivity ranged from $r = 0.636$ to $r = 0.826$ for the body subscale, from $r = 0.695$ to $r = 0.854$ for the psyche subscale and from $r = 0.796$ to $r = 0.900$ for the everyday life subscale.

3.3.4 | Convergent validity

Convergent validity (Table 7) of the Wound-QoL-17 regarding other PROMs was high, showing largest effect sizes for global rating scale ($r = 0.765$, $p < 0.001$, $n = 289$), and the DLQI total score ($r = 0.684$, $p < 0.001$, $n = 294$). Correlation with EQ VAS revealed only moderate effect size ($r = -0.460$, $p < 0.001$, $n = 296$).

TABLE 1 Characteristics of the total group of study participants with chronic wounds ($N = 305$ patients in eight countries).

Variable	Response options	*n*	%
Gender	Male	161	52.8
	Female	143	46.9
	Missing values	1	0.3
Highest educational level	No certificate	7	2.3
	Certificate without university entrance	161	52.8
	Certificate with university entrance	108	35.4
	Other	22	7.2
	Missing values	7	2.3
Occupational status	Full-/part-time job	41	13.4
	Leave	4	1.3
	House	24	7.9
	Retired	200	65.6
	Early	23	7.5
	Unemployed	17	5.6
	Training	1	0.3
	Missing values	5	1.7
Family status	Single	28	9.2
	Permanent relationship	15	4.9
	Married	145	47.5
	Living separately	1	0.3
	Divorced	29	9.5
	Widowed	86	28.2
	Missing values	1	0.3
Having children	Yes	247	81.0
	No	56	18.4
	Missing values	2	0.7
Living situation (multiple responses possible)	Alone	104	34.1
	With partner	145	47.5
	With children	65	21.3
	With other	19	6.2
	Missing values	2	0.7
Living in a nursing home	Yes	25	8.2
	No	274	91.1
	Missing values	2	0.7

Variable	*n*	Mean	SD	Median	Range
Age (years)	302	68.5	13.9	70.0	28.0; 96.0
Working hours/week	36	36.7	12.1	40.0	8.0; 60.0
Number of children	294	1.8	1.4	2.0	0.0; 11.0

Abbreviations: *n*, number of participants; SD, standard deviation.

Correlation between the body subscale and the DLQI symptoms and feelings subscale ($r = 0.618$, $p < 0.001$, $n = 296$) and with the DLQI treatment subscale ($r = 0.467$, $p < 0.001$, $n = 299$) showed large to medium effect sizes; correlation between the psyche subscale and the DLQI personal relationships subscale ($r = 0.374$,

TABLE 2 Descriptive analysis of patient-reported outcomes of $N = 305$ patients.

Variable		*n*	Mean	SD	Median	Range
Global HRQoL rating		292	3.5	1.2	4.0	1.0; 5.0
NRS at dressing change		302	4.3	3.1	4.8	0.0; 10.0
NRS at rest		302	3.4	2.8	3.0	0.0; 10.0
EQ-5D-5L	Polish value set	294	0.7	0.3	0.8	−0.6; 1.0
	Spanish value set	294	0.5	0.3	0.6	−0.4; 1.0
EQ VAS		298	55.4	19.9	50.0	0.0; 100.0
DLQI	Total score	297	10.2	6.6	9.0	0.0; 28.0
	Symptoms and feelings	300	2.8	1.7	3.0	0.0; 6.0
	Daily activities	293	2.4	1.9	2.0	0.0; 6.0
	Leisure	292	2.1	2.0	2.0	0.0; 6.0
	Work and school	296	0.8	1.3	0.0	0.0; 0.3
	Personal relationships	299	1.0	1.5	0.0	0.0; 6.0
	Treatment	303	1.1	1.0	1.0	0.0; 3.0

Abbreviations: DLQI, Dermatology Life Quality Index; EQ VAS, visual analogue scale of the EQ-5D instrument; EQ-5D-5L, 5-level EQ-5D; HRQoL, health-related quality of life; *n*, number of participants; NRS, numeric rating scale; SD, standard deviation.

TABLE 3 Wound type of $N = 305$ patients according to patient and clinician reports (multiple responses possible).

Patient-reported			Clinician-reported		
Wound type	***n***	**%**	**Wound type**	***n***	**%**
Venous ulcer	70	23.0	Ulcus cruris venosum	101	33.1
Arterial ulcer	24	7.9	Ulcus crusis arteriosum	21	6.9
Mixed ulcer	25	8.2	Ulcus cruris mixtum	33	10.8
Diabetic foot ulcer	76	24.9	Diabetic foot ulcer	76	24.9
Decubitus	18	5.9	Decubitus	20	6.6
Other	54	17.7	Other	75	24.6
Unknown	54	17.7	–	–	–
Missing values	5	1.6	Missing values	8	2.6

Abbreviation: *n*, number of participants.

$p < 0.001$, $n = 295$) showed medium effect size; and correlations between the everyday life and the DLQI leisure subscale ($r = 0.482$, $p < 0.001$, $n = 288$) and the DLQI work and school subscale ($r = 0.201$, $p = 0.001$, $n = 291$) showed medium to low effect sizes.

Convergent validity analyses with wound-specific data showed medium effect sizes regarding wound size ($r = 0.381$, $p < 0.001$, $n = 283$) and odour ($r = -0.371$, $p < 0.001$, $n = 296$). Other clinician-reported data showed only small, but statistically significant effects.

3.3.5 | Test–retest reliability

Test–retest reliability was good for the global scale (ICC = 0.771, 95% confidence interval (CI) 0.666–0.842) and the everyday life subscale (ICC = 0.808, 95% CI = 0.736, 0.861), and moderate for the psyche (ICC = 0.703, 95% CI = 0.584, 0.789) and the body subscales (ICC = 0.622, 95% CI = 0.465, 0.734).

3.4 | Wound-QoL-14

3.4.1 | Floor and ceiling effects

In the everyday life subscale, 22 (7.3%) patients achieved the lowest score, indicating a small floor effect, but not in the other (sub)scales ($n = 3$, 1.0% to $n = 13$, 4.3%). Considerable ceiling effects were detectable for the psyche ($n = 39$, 12.9%) and everyday life subscales ($n = 27$, 8.9%), but not for the body subscale ($n = 11$, 3.6%) or the global scale ($n = 4$, 1.3%).

TABLE 4 Wound characteristics (clinician-reported if not stated otherwise) of $N = 305$ patients.

Variable		*n*	%
Wound slough	None	72	23.6
	Present	224	75.7
	Missing values	9	3.0
Wound edge	Irritated	259	84.9
	Not irritated	41	13.7
	Missing values	5	1.7
Wound environment	Irritated	258	84.6
	Not irritated	41	13.7
	Missing values	6	2.0
Odour	None	200	65.6
	Present	100	32.8
	Missing values	5	1.7
Amount of exudate	None	39	12.8
	A little	118	38.7
	Medium	107	35.1
	Strong	32	10.5
	Missing values	9	3.0

Variable	*n*	Mean	SD	Median	Range
Wound size (cm^2)	287	44.2	121.9	9.8	0.1; 1400.0
Wound duration, patient-reported (months)	299	24.9	63.8	6.0	0.0; 600.0
Wound duration, clinician-reported (months)	279	20.0	54.4	6.0	0.0; 600.0

Abbreviations: *n*, number of participants; SD, standard deviation.

3.4.2 | Internal consistency

Internal consistency (Table 6) was good for all scales (global: Cronbach's $\alpha = 0.925$, $n = 276$; everyday life: 0.918, $n = 294$; psyche: 0.881, $n = 294$; body: 0.779, $n = 289$).

3.4.3 | Item selectivity

Item selectivity (Appendix S1) of the global score ranged from $r = 0.548$ to $r = 0.808$ with highest correlations in items on everyday activities ($r = 0.808$), being unhappy ($r = 0.793$) and recreational activities ($r = 0.782$). Lowest correlations were seen in items on disturbing discharge from the wound ($r = 0.548$) and wound smell ($r = 0.562$). Subscale item selectivity ranged from $r = 0.672$ to $r = 0.828$ for body subscale, from $r = 0.842$ to $r = 0.888$ for the psyche subscale and from $r = 0.817$ to $r = 0.902$ for the everyday life subscale.

3.4.4 | Convergent validity

Convergent validity (Table 7) with other PROMs was high, showing largest effect sizes for the global rating scale ($r = 0.751$, $p < 0.001$, $n = 289$) and the DLQI total score ($r = 0.681$, $p < 0.001$, $n = 294$). Correlation with EQ VAS revealed moderate effect size ($r = -0.473$, $p < 0.001$, $n = 296$).

Correlations between the body subscale and the DLQI symptoms and feelings subscale ($r = 0.594$, $p < 0.001$, $n = 297$) and the DLQI treatment subscale ($r = 0.426$, $p < 0.001$, $n = 300$) showed large to medium effect sizes; correlation between the psyche subscale and the DLQI relationships subscale ($r = 0.375$, $p < 0.001$, $n = 295$) showed medium effect size; and correlations between everyday life subscale and the DLQI leisure subscale ($r = 0.501$, $p < 0.001$, $n = 288$) and the DLQI work and school subscale ($r = 0.208$, $p < 0.001$, $n = 292$) showed medium to low effect sizes.

Convergent validity analyses regarding clinical data showed medium effects regarding odour ($r = -0.388$,

TABLE 5 Descriptive characteristics of Wound-QoL items, global scales and subscales of $N = 303$ patients completing the Wound-QoL.

Variable		*n*	*n* (%) quite/very^{+}	Mean	SD	Median	Range
1	My wound hurts	301	128 (42.5)	2.2	1.4	2.0	0.0; 4.0
2	My wound had a bad smell	299	41 (13.7)	1.0	1.3	0.0	0.0; 4.0
3	The discharge from the wound has upset me	299	78 (26.1)	1.6	1.3	1.0	0.0; 4.0
4	The wound has affected my sleep	297	110 (37.0)	1.8	1.5	2.0	0.0; 4.0
5	The treatment of the wound has been a burden to me	301	116 (38.5)	2.0	1.4	2.0	0.0; 4.0
6	The wound has made me unhappy	299	113 (37.8)	1.8	1.4	2.0	0.0; 4.0
7	I have felt frustrated because the wound is taking so long to heal	302	161 (53.3)	2.4	1.4	3.0	0.0; 4.0
8	I have worried about my wound	301	174 (57.8)	2.7	1.3	3.0	0.0; 4.0
9	I have been afraid of the wound getting worse or of getting new wounds	298	175 (58.7)	2.6	1.4	3.0	0.0; 4.0
10^{++}	I have been afraid of hitting the wound against something	300	154 (51.3)	2.3	1.4	3.0	0.0; 4.0
11	I have had trouble moving around because of the wound	299	126 (42.1)	2.0	1.4	2.0	0.0; 4.0
12^{++}	Climbing stairs has been difficult because of the wound	298	128 (43.0)	2.0	1.6	2.0	0.0; 4.0
13	I have had trouble with everyday activities	300	134 (44.7)	2.0	1.5	2.0	0.0; 4.0
14	The wound has limited my recreational activities	301	151 (50.2)	2.2	1.6	3.0	0.0; 4.0
15	The wound has forced me to limit my contact with other people	299	106 (35.5)	1.7	1.5	2.0	0.0; 4.0
16	I have felt dependent on help from others because of the wound	302	139 (46.0)	2.2	1.6	2.0	0.0; 4.0
17^{++}	The wound has been a financial burden to me	303	111 (36.6)	1.8	1.5	2.0	0.0; 4.0
Wound-QoL-17							
	Global score	301	–	2.0	1.0	2.0	0.0; 4.0
	Body subscale	300	–	1.7	1.1	1.6	0.0; 4.0
	Psyche subscale	300	–	2.4	1.1	2.4	0.0; 4.0
	Everyday life subscale	299	–	2.0	1.3	2.2	0.0; 4.0
Wound-QoL-14							
	Global score	301	–	2.0	1.0	2.1	0.0; 4.0
	Body subscale	301	–	1.6	1.1	1.5	0.0; 4.0
	Psyche subscale	300	–	2.4	1.2	2.5	0.0; 4.0
	Everyday life subscale	300	–	2.0	1.3	2.0	0.0; 4.0

Note: $^{+}$Participants who answered with 'quite' or 'very'. $^{++}$Item excluded in Wound-QoL-14.
Abbreviations: *n*, number of participants; SD, standard deviation.

TABLE 6 Internal consistency of global and subscale scores.

	Wound-QoL-17			Wound-QoL-14		
	Number of items	*n*	Cronbach's α	Number of items	*n*	Cronbach's α
Global score	17	273	0.933	14	276	0.925
Body subscale	5	289	0.820	4	289	0.779
Psyche subscale	5	292	0.863	4	294	0.881
Everyday life subscale	6	292	0.927	5	294	0.918

Abbreviation: *n*, number of participants.

TABLE 7 Convergent validity of the Wound-QoL-17 and Wound-QoL-14.

	Wound-QoL-17			Wound-QoL-14		
	r	*p*	*n*	*r*	*p*	*n*
Continuous and ordinal variables						
EQ-5D-5L (Polish value set)$^{+}$	−0.606	<0.001	291	−0.600	<0.001	291
EQ-5D-5L (Spanish value set)$^{+}$	−0.634	<0.001	291	−0.629	<0.001	291
EQ VAS^{+}	−0.460	<0.001	296	−0.473	<0.001	296
DLQI^{+}	0.684	<0.001	294	0.681	<0.001	294
Global rating^{+}	0.765	<0.001	289	0.751	<0.001	289
NRS during change^{+}	0.531	<0.001	299	0.524	<0.001	299
NRS at rest^{+}	0.597	<0.001	299	0.597	<0.001	299
Wound size	0.381	<0.001	283	0.383	<0.001	283
Duration of wound^{++}	0.209	<0.001	275	0.195	0.001	275
Amount of exudate^{++}	0.298	<0.001	292	0.318	<0.001	292
Dichotomous variables						
Wound edge^{++}	−0.256	<0.001	296	−0.241	<0.001	296
Wound environment^{++}	−0.209	<0.001	295	−0.195	0.001	295
Wound cover^{++}	−0.173	0.004	292	−0.168	0.005	292
Odour^{++}	−0.371	<0.001	296	−0.388	<0.001	296

Note: $^{+}$Patient-reported; $^{++}$Clinician-reported.
Abbreviations: DLQI, Dermatology Life Quality Index; EQ VAS, visual analogue scale of the EQ-5D instrument; EQ-5D-5L, 5-level EQ-5D; *n*, number of participants; NRS, numeric rating scale; *p*, significance value; *r*, effect size.

TABLE 8 Test–retest reliability of the Wound-QoL-17 and Wound-QoL-14 in patients with retest completion within 5–9 days after baseline.

	Wound-QoL-17			Wound-QoL-14		
	ICC	95% CI	*n*	ICC	95% CI	*n*
Global scale	0.771	0.665, 0.842	129	0.751	0.635, 0.828	129
Body subscale	0.622	0.465, 0.734	128	0.618	0.460, 0.731	129
Psyche subscale	0.703	0.584, 0.789	129	0.696	0.581, 0.781	129
Everyday life subscale	0.808	0.736, 0.861	128	0.797	0.723, 0.853	128

Abbreviations: 95% CI, 95% confidence interval; ICC, intraclass correlation coefficient; *n*, number of participants.

$p < 0.001$, $n = 296$), wound size ($r = 0.383$, $p < 0.001$, $n = 283$) and amount of exudate ($r = 0.318$, $p < 0.001$, $n = 292$). Other clinician-reported outcomes showed only small, but statistically significant effects.

3.4.5 | Test–retest reliability

Test–retest reliability (Table 8) was good for the global scale (ICC = 0.751, 95% CI = 0.636, 0.828) and the everyday life subscale (ICC = 0.797, 95% CI = 0.723, 0.853), and moderate for the psyche subscale (ICC = 0.696, 95% CI = 0.581, 0.781) and the body subscale (ICC = 0.618, 95% CI = 0.460, 0.731) of the Wound-QoL-14.

3.5 | Country-specific results

Country-specific validation (Appendix S1) could be performed for Austria ($n = 51$), Lithuania ($n = 50$), Poland ($n = 50$), Ukraine ($n = 42$), Slovakia ($n = 41$) and the Netherlands ($n = 37$), but not for Switzerland ($n = 13$) and Spain ($n = 12$). There were no relevant differences in psychometric properties data across countries.

4 | DISCUSSION

The aim of the study was to analyse psychometric properties of the Wound-QoL-17 and the Wound-QoL-14 in a

European sample. Results of psychometric analyses confirm that both Wound-QoL versions are valid instruments for the use in clinical practice and international studies. The validation data in this international cohort are satisfying and show no relevant differences between the 17- and the 14-item version.

None of the items had a remarkably high number of missing values, while previous studies in Dutch and German samples[14,30] found many missing values for the item on climbing stairs (which might be influenced by the physical and the structural conditions of the patients (mobility, functioning) and their residences (e.g. no upper floors, lifts)). In both versions, ceiling effects were seen for psyche and everyday life subscales, highlighting the impact the condition can have on non-physical areas of life, but also indicating that the scales may not be able to completely distinguish between very high and extremely high impairment in these areas.

As in previous studies, internal consistency was lowest for the body subscale,[13,14,17,18] but still internal consistency was good for all scales.

In consistency with previous studies,[14] items on every day and recreational activities showed highest values in item selectivity regarding the Wound-QoL-17 global scale indicating the importance of exerting these activities have on patients' HRQoL. Likewise, the everyday life subscale correlated highest with the Wound-QoL-17 global scale. Wound-QoL-14 showed similar results.

Results on convergent validity for both versions largely confirmed the pre-defined hypotheses with largest effect sizes regarding DLQI, global HRQoL rating and EQ-5D-5L. With regard to pain measures, convergent validity showed large effect sizes; in previous studies, effect size of correlations with pain varied from small to large.[14,16,22] As expected, effect sizes were larger for pain at rest than for pain during dressing change. Odour showed the largest and second largest effect size among the clinical variables; in a previous study,[14] odour was hypothesised to have a high impact on HRQoL but could not be analysed as it had not been assessed. Patient-reported smell (item of the Wound-QoL) correlated higher with the Wound-QoL total score compared with clinician-reported odour but had one of the lowest correlations compared with other Wound-QoL items in item selectivity analysis. This highlights the importance of psychosocial components of HRQoL as compared to the physical and clinical aspects.

Retest results were moderate for body and psyche subscales and good for global scale and everyday life subscale. A previous study revealed higher retest reliability.[20] This difference might be explained by the different settings. While the previous study assessed retest reliability in patients treated by a mobile nursing service throughout routine care, the patients in this study visited ambulatory clinics where they received treatment at the date of baseline assessment. Accordingly, actual change might have occurred during the recall period, which is supported by the decrease in mean scores (results not displayed; with highest decline (−0.33) in body subscale).

The major strength of this study was its international approach, allowing for both a combined analysis of the whole sample of more than 300 patients and a comparison of country-specific results. This validation supports the use of both Wound-QoL versions in European samples. It confirms previous single-country studies confirming validity of the Wound-QoL-17, and it is the first study analysing psychometric properties of the Wound-QoL-14 beyond internal consistency.

Limitations of this study were that only eight instead of 10 countries participated in the study and that not all participating countries reached the targeted sample size, resulting in a sample size of 305 patients with an unequal distribution across countries. While some recruiting centres stated that recruitment of patients posed no problem and they recruited subsequent patients, other stated that the ability to read and answer questionnaires lead to exclusion of potential participants according to the study inclusion criteria. Lower ability of patients to read and answer questionnaires has also brought about physicians or nurses to read out the questionnaire to some patients. As self-completion and answering to read-out version of the Wound-QoL might result in different response behaviour,[14] documenting the completion mode might be useful to assess how comparable results of different time points are or whether the information might be influenced by a helping person.

The Wound-QoL is a frequently used instrument in clinical practice and research. On item level, patients' answers can be used for treatment planning and enhancing compliance; on scale level, scores can be used to evaluate treatment. Profound results about psychometric properties are necessary to confirm the reliability and validity of patient-reported data. This manuscript adds comprehensive validation data for the Wound-QoL-17 to the existing body of literature; it is the first study analysing these properties on a European level and including data on Central/Eastern European countries. For the Wound-QoL-14, it is the first study analysing psychometric properties such as convergent validity and test–retest reliability. As this short version has only been established after the start of the present study, the data here present a 'virtual validation' (i.e. patients completed the longer version and responses on the items included in the shorter version were analysed[11]). In a future study, the Wound-QoL-14 should be completed in its original length to confirm its good psychometric properties found

in this study, as it cannot be ruled out that the overall item set resulted in slightly different response behaviour.

In clinical practice where time is rare, the Wound-QoL-14 might be preferable considering its good psychometric properties and brevity. The availability of various language version allows the use of this questionnaire not only in international studies but also in clinical practice when foreign language patients are being treated.

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CONFLICT OF INTEREST STATEMENT

TMJ, VK, SV, LR, PC, MJ, CVM, SA, MB and ECM report to have no conflicts of interest. AR has been a consultant or speaker for AbbVie, Bioderma, Boehringer Ingelheim, Celgene, Chema Elektromet, Eli Lilly, Galderma, Janssen, Leo Pharma, Medac, Menlo Therapeutics, Novartis, Pierre-Fabre, Sandoz and Trevi Therapeutics; and principal investigator or subinvestigator in clinical trials sponsored by Abbvie, Alvotech, Amgen, AnaptysBio, Argenx, Biothera, BMS, Celgene, Celltrion, Dermira, Galderma, Inflarx, Janssen, Kiniksa, Kymab, Leo Pharma, Novartis, Pfizer, Trevi Therapeutics, UCB. KS participated in clinical trials as subinvestigator sponsored by Amgen, Anaptys, Almirall, Celltrion, Galderma, Kiniksa, Novartis, Trevi Therapeutics and was an invited speaker by Medac and Novartis. MA has received fees for consulting and/or lectures and/or studies from the following companies: 3 M Medica, AOK Bundesverband, Bayer Healthcare, Beiersdorf, Birken, Bode, B. Braun, BSNmedical/Essity, BVmed, Coloplast, DAK, Diabet concept, Gerromed, GlaxoSmithKline, Johnson & Johnson, Lohmann & Rauscher, medi, Medovent, Mölnlycke, Smith & Nephew, Schülke & Mayr, Söring, Sorbion, Systagenix, Uluru, Urgo. Project proposal has been submitted by MA. CB is project lead of the HAQOL study, which has been partly funded by the EADV.

DATA AVAILABILITY STATEMENT

Data are available on reasonable request from the corresponding author.

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REFERENCES

1. Lazarus GS, Cooper DM, Knighton DR, et al. Definitions and guidelines for assessment of wounds and evaluation of healing. *Wound Repair Regen*. 1994;2(3):165-170.
2. Dissemond J, Bültemann A, Gerber V, Jäger B, Münter C, Kröger K. Definitionen für die Wundbehandlung. *Hautarzt*. 2016;67(3):265-266.
3. Werdin F, Tenenhaus M, Rennekampff H-O. Chronic wound care. *Lancet*. 2008;372(9653):1860-1862.
4. Martinengo L, Olsson M, Bajpai R, et al. Prevalence of chronic wounds in the general population: systematic review and meta-analysis of observational studies. *Ann Epidemiol*. 2019;29:8-15.
5. Olsson M, Järbrink K, Divakar U, et al. The humanistic and economic burden of chronic wounds: a systematic review. *Wound Repair Regen*. 2019;27(1):114-125.
6. Augustin M, Mayer A, Goepel LM, Baade K, Heyer K, Herberger K. Cumulative life course impairment (CLCI): a new concept to characterize persistent patient burden in chronic wounds. *Wound Med*. 2013;1:2-6.
7. Nabuurs-Franssen MH, Huijberts MSP, Nieuwenhuijzen Kruseman AC, Willems J, Schaper NC. Health-related quality of life of diabetic foot ulcer patients and their caregivers. *Diabetologia*. 2005;48(9):1906-1910.
8. Rich K, Upton D. Subjective wellbeing amongst informal caregivers of people with wounds: a cross-sectional survey. *Wound Pract Res*. 2017;25:172-178.
9. Jockenhöfer F, Gollnick H, Herberger K, et al. Aetiology, comorbidities and cofactors of chronic leg ulcers: retrospective evaluation of 1 000 patients from 10 specialised dermatological wound care centers in Germany. *Int Wound J*. 2016;13(5):821-828.
10. Edwards H, Finlayson K, Skerman H, et al. Identification of symptom clusters in patients with chronic venous leg ulcers. *J Pain Symptom Manage*. 2014;47(5):867-875.
11. Blome C, Baade K, Debus ES, Price P, Augustin M. The "wound-QoL": a short questionnaire measuring quality of life in patients with chronic wounds based on three established disease-specific instruments. *Wound Repair Regen*. 2014;22(4):504-514.
12. Klein TM, Andrees V, Kirsten N, Protz K, Augustin M, Blome C. Social participation of people with chronic wounds: a systematic review. *Int Wound J*. 2021;18(3):287-311.
13. von Stülpnagel CC, Da Silva N, Augustin M, et al. Assessing the quality of life of people with chronic wounds by using the cross-culturally valid and revised wound-QoL questionnaire. *Wound Repair Regen*. 2021;29(3):452-459.
14. Amesz SF, Klein TM, Meulendijks AM, et al. A translation and preliminary validation of the Dutch wound-QoL questionnaire. *BMC Dermatol*. 2020;20(1):5.
15. Augustin M, Conde Montero E, Zander N, et al. Validity and feasibility of the wound-QoL questionnaire on health-related quality of life in chronic wounds. *Wound Repair Regen*. 2017;25(5):852-857.
16. Conde Montero E, Sommer R, Augustin M, et al. Validación de la versión española del cuestionario Wound-QoL. *Actas Dermosifiliogr*. 2021;112(1):44-51.

17. Fagerdahl A-M, Bergström G. Translation and validation of a wound-specific, quality-of-life instrument (the wound-QoL) in a Swedish population. *Ostomy Wound Manage*. 2018;64(5):40-46.
18. Gamus A, Kaufman H, Keren E, Brandin G, Peles D, Chodick G. Validation of "wound QoL" Hebrew version disease-specific questionnaire for patients with lower extremity ulcerations. *Int Wound J*. 2018;15(4):600-604.
19. Knudsen JT, Johansen CW, Hansen AØ, Eshoj HR. The Danish wound-quality of life (wound-QoL) questionnaire: translation and psychometric properties. *Wound Repair Regen*. 2021;29(6):973-984.
20. Sommer R, Augustin M, Hampel-Kalthoff C, Blome C. The Wound-QoL questionnaire on quality of life in chronic wounds is highly reliable. *Wound Repair Regen*. 2017;25(4):730-732.
21. Sommer R, Hampel-Kalthoff C, Kalthoff B, et al. Differences between patient- and proxy-reported HRQoL using the Wound-QoL. *Wound Repair Regen*. 2018;26(3):293-296.
22. Sommer R, von Stülpnagel CC, Fife CE, et al. Development and psychometric evaluation of the U.S. English wound-QoL questionnaire to assess health-related quality of life in people with chronic wounds. *Wound Repair Regen*. 2020;28(5):609-616.
23. Finlay AY, Khan GK. Dermatology life quality index (DLQI)—a simple practical measure for routine clinical use. *Clin Exp Dermatol*. 1994;19(3):210-216.
24. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res*. 2011;20(10):1727-1736.
25. Golicki D, Jakubczyk M, Graczyk K, Niewada M. Valuation of EQ-5D-5L health states in Poland: the first EQ-VT-based study in central and Eastern Europe. *Pharmacoeconomics*. 2019;37(9):1165-1176.
26. Ramos-Goñi JM, Craig BM, Oppe M, et al. Handling data quality issues to estimate the Spanish EQ-5D-5L value set using a hybrid interval regression approach. *Value Health*. 2018;21(5):596-604.
27. Terwee CB, Bot SDM, de Boer MR, et al. Quality criteria were proposed for measurement properties of health status questionnaires. *J Clin Epidemiol*. 2007;60(1):34-42.
28. Cohen J. *Statistical Power Analysis for the Behavioral Sciences*. Lawrence Erlbaum Associates; 1988.
29. Koo TK, Li MY. A guideline of selecting and reporting Intraclass correlation coefficients for reliability research. *J Chiropr Med*. 2016;15(2):155-163.
30. Augustin M, Baade K, Herberger K, et al. Use of the WoundQoL instrument in routine practice: feasibility, validity and development of an implementation tool. *Wound Med*. 2014;5:4-8.

SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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