

A translation and preliminary validation of the Dutch Wound-QoL questionnaire

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Abstract

Background Chronic wounds have a major impact on patients' health-related quality of life (HRQoL). Therefore, measuring HRQoL is an indispensable part of the treatment of patients with chronic wounds.

Objectives To translate and validate the Wound-QoL, a wound-specific HRQoL questionnaire, in a Dutch population.

Methods The Wound-QoL was translated into Dutch according to the international standards. Patients with chronic wounds were asked to complete questionnaires at baseline (T0) and after 6 weeks (T1), including Wound-QoL, EQ-5D-3L (a generic questionnaire to measure HRQoL) and a visual analogue scale (VAS) measuring wound pain. If patients were not able to complete the questionnaire by themselves, it was read out to them by a nurse. Further data were obtained from medical records.

Results Of the 120 patients included, 64 (53.3%) completed the questionnaire by themselves. To 55 patients (45.8%), the questionnaire was read out. The internal consistency of the Wound-QoL global score was high at both time points (T0: Cronbach's $\alpha = 0.89$, T1: Cronbach's $\alpha = 0.92$). The item selectivity for global score ranged from $r = 0.25$ to $r = 0.77$ at T0 and from $r = 0.40$ to $r = 0.79$ at T1. Overall, the self-completion and read-out subgroups showed similar internal consistency and item selectivity scores. With regard to convergent validity, significant correlations were found between Wound-QoL and EQ-5D-3L (T0: $r = -0.45$, $p < 0.001$, T1: $r = -0.50$, $p < 0.001$) as well as between Wound-QoL and pain VAS (T0: $r = 0.23$, $p = 0.012$, T1: $r = 0.37$, $p = 0.001$) at both time points. Responsiveness analyses showed significant correlations between changes in Wound-QoL and changes in EQ-5D-3L ($r = -0.37$, $p < 0.001$), pain VAS ($r = 0.24$, $p = 0.044$) and wound size ($r = 0.24$, $p = 0.013$). The self-completion and read-out subgroups showed differences in convergent validity and responsiveness.

Conclusions The results indicate that the Dutch version of the Wound-QoL has positive psychometric properties. However, more research is needed to further explore the differences between self-completed and read-out questionnaires.

Background

Chronic wounds are lesions of the skin and subcutaneous tissue that show insufficient healing two to four weeks after occurrence according to the Dutch recommendation¹. They may have various causes, such as venous or arterial insufficiency, diabetes mellitus, trauma, malignancy, self-mutilation or physical pressure¹. A meta-analysis² including several worldwide studies showed a pooled prevalence of 2.21 per 1,000 persons with chronic wounds per year. A slightly higher prevalence of approximately 500,000 patients per year was found in the Netherlands³. However, one must be careful not to compare prevalence rates with each other, because there is no uniform definition for the term 'chronic wound'. The prevalence of chronic wounds increases with age. The highest prevalence rates occur in people above the age of 65⁴. Therefore, prevalence rates are likely to increase due to the ageing of the Dutch population⁵.

Patients with chronic wounds often experience impairments such as pain, the necessity for frequent dressing changes and mobility limitation, which negatively impact the patients' health-related quality of life (HRQoL)^{6,7}.

HRQoL is a patient-reported outcome (PRO). It is considered an important outcome measure of medical treatment in addition to the clinical outcome measures⁸. Nowadays, HRQoL questionnaires are widely used and play a major role in healthcare decisions and treatment evaluation⁹. The use of validated questionnaires to measure patient characteristics and treatment outcomes from the patients' perspective is necessary in the treatment of chronic wounds as well¹⁰⁻¹². However, a validated, easy-to-use HRQoL questionnaire for clinical use is not available in the Netherlands.

In view of the age composition of the patient group with chronic wounds as well as the necessity to regularly assess HRQoL in routine care, brief and easy-to-use questionnaires are recommended¹³.

For this purpose, the Wound-QoL questionnaire (Fig. 1) has been developed based on three more extensive questionnaires for patients with wounds (the Cardiff Wound Impact Schedule (CWIS)¹², the Freiburg Life Quality Assessment for wounds (FLQA-W)¹⁰ and the Wuerzburg Wound Score (WWS)¹⁴. The Wound-QoL^{15,16} consists of 17 questions based on which a total scale score and three subscale scores ('body', 'psyche', and 'everyday life') can be calculated. The Wound-QoL was developed to create a brief instrument. The Wound-QoL questionnaire has been translated into 20 languages (available on the website: www.wound-qol.com). However, a validated Dutch translation of the Wound-QoL has not yet become available.

Therefore, the aim of this study was to translate and validate the Wound-QoL questionnaire for Dutch people suffering from chronic wounds'.

Insert Fig. 1

Methods

We translated the validated German Wound-QoL questionnaire into Dutch according to the international standards for cross-cultural adaptations of outcome instruments¹⁷. The translation process included two forward and two backward translations and harmonization of these versions.

In contrast to the standardized translation process, patients in pre-tests requested that the Dutch phrasing of the item "the wound has affected my sleep" was changed so that the phrasing of the item corresponded to the response scale. Therefore, our study validated the questionnaire including this minor change in the phrasing of one particular item.

In order to validate the Dutch version of the Wound-QoL, we recruited patients with chronic wounds (of different aetiologies) who were able to speak and understand Dutch. Patients were recruited from a home care organization and were treated in different healthcare centres in the Netherlands. The aim was to

recruit no fewer than 100 patients, which is considered an adequate sample size for analysing various psychometric properties¹⁸. Recruitment took place from August 2018 to May 2019.

Patients were asked to complete the questionnaires during their visits at the moment of inclusion (T0) and after six weeks (T1). The first questionnaire consisted of sociodemographic questions (weight, height, number of people in the household), the Wound-QoL, the generic HRQoL instrument EQ-5D-3L and a visual analogue scale (VAS) measuring the patients' worst pain during the day. The second questionnaire consisted of the same instruments except sociodemographic questions. Further information further data were obtained from medical records (age, gender, smoking habits, compression therapy, wound diagnosis, medication, comorbidities). Additionally, the size of the wound surface was measured at T0 and T1 by using a camera (inSight ® by WoundWorks). For patients with various wounds, the size of the largest wound was measured.

A number of patients completed the questionnaires by themselves (self-completion group). If patients were not able or did not wish to complete the questionnaire by themselves, nurses read out the questionnaires to the patients and wrote down their answers (read-out group).

For a small subgroup of participants, the time of completion was measured.

All patients gave prior written informed consent to participate in the study. The study has been approved by the medical ethical committee of the Isala Clinics (No. 180916; Zwolle, The Netherlands).

Statistical analyses were performed by using SPSS 25. The Wound-QoL scores were calculated by averaging the respective items, if at least 75% of the items had been answered. The EQ-5D-3L index was calculated by using the utility algorithm for the Netherlands. The following properties were analysed in order to validate the Dutch Wound-QoL questionnaire: floor and ceiling effects (i.e. percentage of patients with the highest/lowest scores), internal consistency (i.e. Cronbach's alpha for the global scale and for each subscale), item selectivity (i.e. correlation of the global score with each item; correlation of the subscale scores with each respective item; correlation of the global score with the subscale scores), convergent validity (i.e. correlation of the global score with the EQ-5D-3L score, score of pain VAS, the size of the wound surface), and responsiveness (i.e. correlation of changes between T0 to T1 in the global score with changes in the EQ-5D score, VAS score and the size of the wound surface).

For convergent validity, hypotheses were formulated about the direction and relative strength magnitude of the correlations between the Wound-QoL score comparator instruments. It was hypothesized that higher EQ-5D-3L scores would be associated with lower Wound-QoL scores, whereas higher pain VAS scores and larger wound size would be associated with higher Wound-QoL scores. With regard to the relative magnitude strength of the correlations, it was assumed that the correlation between Wound-QoL scores and EQ-5D-3L scores were highest, because both instruments represent multidimensional HRQoL constructs. It was assumed that the correlation between Wound-QoL and pain VAS was the second strongest. Although pain might cause major limitations for patients, it might not be the only wound-related aspect affecting HRQoL. The weakest correlation was expected to be found between Wound-QoL

and the wound size. With regard to responsiveness, it was hypothesized that the directions and relative magnitudes of change in the instruments would correspond to those of convergent validity.

Results

We included 120 patients. Sixty-four of them (53.3%) completed the questionnaire by themselves. To 55 of them (45.8%), nurses read out the questionnaire. For one patient (0.8%), there is no information about the mode of questionnaire completion. The gender distribution was almost equal (n = 63, 52.5% women). The patients had an average age of 73 ± 14 years (min = 18, max = 98). On average, the wound size decreased from 9.88 cm² at T0 to 6.84 cm² at T1 (Table 1). The most common diagnoses (Table 2) were diabetic foot ulcer (n = 37, 30.8%), venous ulcer (n = 20, 16.7%) and ulcer caused by trauma (n = 19, 15.8%). The majority of wounds were located on the lower legs (n = 61, 50.8%) and feet (n = 48, 40.0%). The most frequent comorbidities (Table 2) were cardiovascular diseases (n = 81, 67.5%), diabetes (n = 58, 48.3%) and vascular diseases (n = 53, 44.2%).

Insert Table 1 and Table 2

Table 1: Sociodemographic and wound-specific descriptive statistics for the total sample and subgroups

¹ p-value according to the Chi-square test, ² p-value according to the unpaired t-test

Table 2: Wound diagnoses and comorbidities at baseline

¹ Percentages do not sum up to 100%, because multiple answers were possible.

Number of missing values

Of the seventeen items, nine items at T0 and eight items at T1 showed no missing values. Missing values for the other items ranged from 0.8–2.5% of patients. Only one item ('climbing stairs has been difficult because of the wound') showed a large number of missing values (T0: 29.2%, T1: 25.0%). All patients with missing values for this item filled in or stated during the interview that this item was not applicable to their situation, even though this was not a response option in the Wound-QoL.

Floor and ceiling effects

The global score showed no ceiling effect at either time point and a minor floor effect only at T1 (0.8%). Although the 'body' and 'psyche' subscales did not show ceiling effects at T0, the 'psyche' subscale showed a minor ceiling effect at T1 (0.8%). The 'everyday life' subscale showed minor ceiling effects at both time points (T0: 1.7%, T1: 3.4%). All subscales showed floor effects at both T0 (body: 12.5%, psyche: 9.2%, everyday life: 6.7%) and T1 (21.7%, 7.5%, 11.1% respectively). Floor effects in 'body' and 'everyday life' subscales were less pronounced in the patients who completed the questionnaire by themselves (T0: 6.3%, 4.7%, T1: 18.8%, 8.1% respectively) compared to the patients in the read-out group (T0: 20.0%, 9.3%, T1: 25.5%, 14.8% respectively).

Changes in the mean scores

The mean values decreased over time for both Wound-QoL global score (T0: 1.29, T1: 1.12) and Wound-QoL subscale scores (body: T0: 0.98, T1: 0.81, psyche: T0: 1.38, T1: 1.27, everyday life: T0: 1.59, T1: 1.36). The T-test results revealed significant improvements for the global score ($t(119) = 2.566, p = 0.012$), the 'body' subscale ($t(119) = 2.221, p = 0.028$) and the 'everyday life' subscale ($t(119) = 2.500, p = 0.014$), but not for the 'psyche' subscale ($t(119) = 1.136, p = 0.258$).

When we consider each of the subgroups, a significant change was observed in the self-completion group (global score: $p = 0.005$, body: $p = 0.038$, everyday life: $p = 0.002$, psyche: $p = 0.076$), but not in the read-out group (global score: $p = 0.820$, body: $p = 0.371$, everyday life: $p = 0.783$, psyche: $p = 0.404$).

Internal consistency

The internal consistency of the Wound-QoL global score was high at both times points (T0: $\alpha = 0.889$, T1: $\alpha = 0.918$). With regard to the subscales, the internal consistency was highest for the 'everyday life' subscale (T0: $\alpha = 0.895$, T1: $\alpha = 0.925$), followed by the 'psyche' subscale (T0: $\alpha = 0.794$, T1: $\alpha = 0.811$) and the 'body' subscale (T0: $\alpha = 0.673$, T1: $\alpha = 0.687$). The self-completed and read-out questionnaires showed the same patterns.

Item selectivity

The item selectivity of the items of the global score ranged from $r = 0.251$ to $r = 0.768$ at T0 and from $r = 0.395$ to $r = 0.793$ at T1. The items with the highest correlation coefficients were: 'I have had trouble with everyday activities because of the wound' (T0: $r = 0.768$, T1: $r = 0.793$), 'the wound has limited my recreational activities' (T0: $r = 0.760$, T1: $r = 0.723$), 'the wound has forced me to limit my contact with other people' (T0: $r = 0.754$, T1: $r = 0.727$) and 'I have had trouble moving around because of the wound' (T0: $r = 0.712$, T1: $r = 0.728$). It should also be noted that these four items showed the highest correlation coefficients in both the self-completion and the read-out group.

The item selectivity for the 'body' subscale ranged from $r = 0.369$ to $r = 0.769$ at T0 and from $r = 0.515$ to $r = 0.775$ at T1; for the 'psyche' subscale, it ranged from $r = 0.677$ to $r = 0.778$ at T0 and from $r = 0.593$ to $r = 0.807$ at T1 and for the 'everyday life' subscale, it ranged from $r = 0.703$ to $r = 0.890$ at T0 and from $r = 0.707$ to $r = 0.870$ at T1. The correlation between the global scale and subscales was highest for the 'everyday life' subscale (T0: $r = 0.867$, T1: $r = 0.874$), followed by the 'psyche' subscale (T0: $r = 0.801$, T1: $r = 0.801$) and the 'body' subscale (T0: $r = 0.632$, T1: $r = 0.689$).

Item selectivity generally showed minor effects and was similar for both the self-completion and the read-out subgroup.

Convergent validity

The correlation between EQ-5D-3L and Wound-QoL was significant (T0: $r = -0.451, p < 0.001$, T1: $r = -0.501, p < 0.001$). The same goes for the correlation between pain VAS and Wound-QoL (T0: $r = 0.232, p = 0.012$,

T1: $r = 0.372$, $p = 0.001$). Although the correlation between the wound size and Wound-QoL was significant at T1 ($r = 0.228$, $p = 0.015$), it was not significant at T0 ($r = 0.124$, $p = 0.178$). These correlations with the EQ-5D-3L represent moderate to large effect sizes, whereas the other correlations represent small to moderate effect sizes¹⁹.

For the self-completion subgroup, the correlation between EQ-5D-3L and Wound-QoL was significant at both time points (T0: $r = -0.611$, $p < 0.001$, T1: $r = -0.501$, $p < 0.001$). For the read-out subgroup, the correlation between EQ-5D-3L and Wound-QoL was significant at both time points as well (T0: $r = -0.306$, $p = 0.023$, T1: $r = -0.556$, $p < 0.001$). Additionally, for the read-out subgroup, the correlation between pain VAS and Wound-QoL was significant at both time points (T0: $r = 0.357$, $p = 0.008$, T1: $r = 0.486$, $p = 0.003$). The correlations with the EQ-5D-3L again represent moderate to large effect sizes, whereas the correlations with the pain VAS represent moderate effect sizes¹⁹. Table 3 shows the results regarding convergent validity for the total group and the subgroups.

Insert Table 3

Table 3: Convergent validity between the Wound-QoL total score and EQ-5D-3L, pain VAS and wound size in the total sample, self-completion subgroup and read-out subgroup

Significant results are marked in bold; r : Spearman correlation coefficient; n : number of patients; VAS: Visual Analogue Scale

Responsiveness

Significant correlations were found between changes in Wound-QoL and changes in EQ-5D-3L ($r = -0.373$, $p < 0.001$), changes in pain VAS ($r = 0.239$, $p = 0.044$) and changes in wound size ($r = 0.235$, $p = 0.013$). Although the effect sizes were moderate for correlations between changes in Wound-QoL and changes in EQ-5D-3L, the effect sizes were small for the correlations between changes in Wound-QoL and changes in pain VAS and wound size.

For the self-completion subgroup, only the correlation between changes in Wound-QoL and changes in EQ-5D-3L was significant ($r = -0.408$, $p = 0.001$). The effect size was moderate. For the read-out subgroup, the correlation between changes in Wound-QoL and changes in EQ-5D-3L ($r = -0.285$, $p = 0.037$), as well as the correlation between changes in Wound-QoL and changes in wound size ($r = 0.290$, $p = 0.037$), were significant, each representing small effect sizes. Table 4 shows the results regarding responsiveness for the total sample and the subgroups.

Insert Table 4

Table 4: Responsiveness validity between the Wound-QoL total score and EQ-5D-3L, pain VAS, and wound size in the total sample, self-completion subgroup and read-out subgroup.

Significant results are marked in bold; r: Spearman correlation coefficient; n: number of patients; VAS: Visual Analogue Scale

Time of completion

For nine patients, the time needed to complete the Wound-QoL questionnaire was recorded. The time needed ranged from 0:57 minutes (self-completion) to 3:53 minutes (read out) at T0.

Discussion

The aim of this study was to translate the Wound-QoL questionnaire into Dutch and to test the validity of the translated version. Overall, the results showed that the Dutch Wound-QoL version is a valid instrument that only takes little time to complete. The Dutch Wound-QoL showed a good internal consistency and a small to moderate yet significant convergent validity with the EQ-5D-3L for the total sample. These results are similar to those from the validation study of the Swedish Wound-QoL²⁰. Additionally, the results of the present study are similar with the results regarding the German original version¹⁶.

Similar to previous studies²⁰, only the item about “climbing stairs” showed a high number of missing values. Patients who completed the questionnaire by themselves often added a comment next to this item. Patients to whom the questionnaire was read out expressed during the interview with a nurse that this item did not apply to them (e.g. because climbing the stairs was not part of their daily routine). However, further analyses (not shown in the results section) revealed that the exclusion of this item would not impact the overall results.

For convergent validity and responsiveness analyses, Dutch wound-specific questionnaires other than the Dutch version of the Wound-QoL are not available. Therefore, a generic HRQoL instrument (EQ-5D-3L) and wound-specific data were used. Overall, formulated hypotheses were confirmed. Significant yet moderate correlations between Wound-QoL and the pain VAS show that wound pain is not the only wound characteristic influencing disease-specific HRQoL. Stronger correlations between generic and wound-specific HRQoL show that both types of HRQoL adequately reflect an overall picture of the patient’s situation. However, differences between these constructs underlined that the generic HRQoL is influenced by other aspects than the wound as well. Additionally, convergent validity analyses showed no significant correlation between Wound-QoL and wound size. This could mean that the physical impact (e.g. pain, odour) and the visible impact (e.g. exudate) of a wound is more burdensome than the wound size itself¹⁴. However, improvements in any of these characteristics (generic HRQoL, pain, wound size) were correlated with improvements in the wound-specific HRQoL according to the Wound-QoL.

For several psychometric properties, we observed differences between the patients who completed the questionnaire by themselves and those to whom the questionnaire was read out. With regard to floor effects, change in mean scores, convergent validity and responsiveness in particular, discrepancies were found between the two subgroups. The sample characteristics showed that the patients in the read-out subgroup were significantly older and had wounds of longer duration than the other subgroup. Therefore,

it cannot be decided whether the interview reduced the validity of the questionnaire or structural differences between the two subgroups are causing these discrepancies. This could be investigated in future studies, in which a patient sample is randomized into a self-completion and a read-out group.

Finally, it should be noted that this validation study analysed psychometric properties of the total scale and subscales, which serves research and evaluation purposes in particular. However, we recommend that the patients' responses are considered on an item level for routine care purposes as well, as each aspects can be of great importance for individuals⁷. Therefore, the patients' responses to items about physical burden (e.g. odour, exudate), emotional burden (e.g. frustration, worries) and limitations in activities of daily living (e.g. leisure activities, contact with others) should be considered for shared decision-making and joint goal setting.

One of the strengths of this study is that we reached the targeted size of the total sample. Additionally, each subgroup (self-completion and read-out) consisted of more than 50 patients, representing a good sample size for analysing psychometric properties¹⁸.

A limitation of this study is the phrasing of one item ("the wound has affected my sleep") being slightly changed and, therefore not being in accordance with, the standardized translation process¹⁵.

Overall, this study indicates that the Dutch Wound-QoL questionnaire is a valid instrument for measuring the HRQoL of patients with chronic wounds. However, the study also shows different outcomes between self-completed and read-out questionnaires. In further studies, the validity of different modes of questionnaire completion should be investigated. Furthermore, this should raise awareness about new modes of questionnaire completion for people who are not able to complete questionnaires themselves.

Conclusions

The results indicate that the Dutch version of the Wound-QoL has positive psychometric properties. However, more research is needed to further explore the differences between self-completed and read-out questionnaires.

Abbreviations

CWIS the Cardiff Wound Impact Schedule.

FLQA-W the Freiburg Life Quality Assessment for wounds.

HRQoL health-related quality of life.

n number of patients.

PRO patient-reported outcome.

p significance level.

r Spearman correlation coefficient.

T0 Patients were asked to complete the questionnaires during their visits at the moment of inclusion

T1 Patients were asked to complete the questionnaires during their visits after six weeks

VAS visual analogue scale.

WWS The Wuerzburg Wound Score

Declarations

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Ethics approval and consent to participate

All patients gave prior written informed consent to participate in the study. The study has been approved by the medical ethical committee of the Isala Clinics (No. 180916; Zwolle, The Netherlands).

Consent for publication not applicable.

.Availability of data and material

On request from corresponding author.

Competing interests

The authors declare that they have no conflict of interest.

Authors' contributions

SA has collected data for the study, has interpreted the data and has drafted major parts of the work. TK has conducted analysis of data, has interpreted the data, and has drafted major parts of the work and revised it. AM has conducted additional analysis and interpretation of data and revised the manuscript. TN has made a substantial contribution by performing the translation process of the original Wound-QoL. CB has interpreted data and revised the work. PF has supervised the process from conception to writing of the manuscript. CM has made major contribution to the design of the study, has interpreted data, and has revised the work. The language centre of the University of Groningen has corrected the manuscript with regard to the English language.

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Authors' information not applicable.

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Tables

Due to technical limitations, tables are only available as a download in the supplemental files section.

Figures

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"/>				
2	...my wound had a bad smell	<input type="radio"/>				
3	...there was a disturbing discharge from the wound	<input type="radio"/>				
4	...the wound has affected my sleep	<input type="radio"/>				
5	...the treatment of the wound has been a burden to me	<input type="radio"/>				
6	...the wound has made me unhappy	<input type="radio"/>				
7	...I have felt frustrated because the wound is taking so long to heal	<input type="radio"/>				
8	...I have worried about my wound	<input type="radio"/>				
9	...I have been afraid of the wound getting worse or of new wounds appearing	<input type="radio"/>				
10	...I have been afraid of knocking the wound	<input type="radio"/>				
11	...I have had trouble moving about because of the wound	<input type="radio"/>				
12	...climbing stairs has been difficult because of the wound	<input type="radio"/>				
13	...I have had trouble with day-to-day activities because of the wound	<input type="radio"/>				
14	...the wound has limited my leisure activities	<input type="radio"/>				
15	...the wound has forced me to limit my activities with others	<input type="radio"/>				
16	...I have felt dependent on help from others because of the wound	<input type="radio"/>				
17	...the wound has been a financial burden to me	<input type="radio"/>				

Figure 1

The English version of the Wound-QoL questionnaire (for usage, please contact PD Dr Christine Blome: c.blome@uke.de)

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [Table3.docx](#)
- [Table1.docx](#)
- [Table2.docx](#)
- [Table4.docx](#)