Validation of the Dutch translation of the Cardiff wound impact schedule for evaluation of the health-related quality of life of patients with chronic wounds

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Validation of the Dutch translation of the Cardiff wound impact schedule for evaluation of the health-related quality of life of patients with chronic wounds

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Abstract

The aim of this study was to validate a Dutch translation of the Cardiff wound impact schedule (CWIS), a disease-specific instrument to measure the health-related quality of life (HRQoL) in patients with chronic leg ulcers. To achieve this, the original instrument was translated. A total of 83 patients with chronic lower leg ulcers were included and completed the translated instrument and SF36 at baseline after assessment of their wound severity. Follow-up was performed 1 week after inclusion. The psychometric properties of the instrument were assessed. Construct validity was positively evaluated by an expert panel. Face validity was positively evaluated in a cognitive debriefing of a pilot group. Discriminant validity was assessed by correlating 1-year amputation risk according to the Wound, Ischaemia, foot Infection classification system with the instrument scores. Significant correlation could not be proven. Criterion validity was assessed by correlating domain scores of the instrument with domain scores of the gold standard: SF36. Moderate to high correlation was calculated for most domains of the instrument. Test-retest reliability and internal consistency were evaluated as acceptable. In conclusion, the Dutch translation of the CWIS is a valid and reliable disease-specific instrument to assess the HRQoL in patients with chronic lower leg ulcers.

KEYWORDS

diabetic foot, foot ulcer, peripheral arterial disease, quality of life, wound infection

1 | INTRODUCTION

A chronic wound is, among alternative definitions, defined as a wound that does not follow an orderly and timely reparative process to produce anatomic and functional integrity within a period of 3 months.[1] The most commonly occurring types of chronic wounds are diabetic foot ulcers, venous ulcers, and pressure ulcers.[2] The estimation is that the lifetime risk of developing a chronic wound is 1% in industrialised countries.[3] The care for patients with chronic wounds places a substantial burden on health care systems worldwide: treatment is often labour intensive and expensive, and complications can lead to minor or major amputations, morbidity,

and mortality. The treatment costs for patients with chronic wounds have been estimated to account for around 1% to 3% of the total health care expenses in developed countries. A recently published systematic review found that the cost burden could mainly be attributed to amputations for patients with diabetes-related chronic wounds. The hospital admittance costs for a diabetes-related amputation for one patient ranged from US $12 851 to US $16 267 (median). Next to this direct economic burden, there is also an indirect cost to society: chronic wounds can, for example, lead to loss of productivity, inability to perform certain work tasks, and may even lead to early retirement.[4]

Chronic wounds can also have a substantial impact on the health-related quality of life (HRQoL) of patients. This is also the case for a subset of chronic wounds: chronic leg wounds. Evidence suggests that leg ulceration leads to a deterioration of quality of life in the physical, occupational, social, and psychological domains.[5] There are two basic methods to measure and quantify HRQoL: using generic instruments and disease-specific instruments.[6] Generic instruments cover the whole spectrum of function, disability, and distress that is relevant to the quality of life. Disease-specific instruments focus on specific aspects of health status. Both instruments have been used to investigate HRQoL in patients with chronic leg ulceration, but disease-specific instruments are considered to have a higher chance of gathering clinically relevant information related to the specific disease and contain items which are viewed as highly relevant to this specific population.[5]

Price and Harding developed the Cardiff wound impact schedule (CWIS) in 2004; it is a disease-specific questionnaire that focuses on chronic leg ulcers irrespective of aetiology and diabetic foot ulcers.[7] It consists of questions in the following domains: social life, well-being, physical symptoms and daily living, overall HRQoL, and satisfaction with overall HRQoL. The CWIS has been translated and validated in the native language of several countries and is considered a valid and reliable instrument to measure HRQoL in patients with acute wounds, chronic leg ulcers, and diabetic foot ulcers.[7]

The purpose of this study is to translate the CWIS to Dutch and validate this version in a Dutch population. Its major goal is to later be able to use the instrument for further clinical research to subjectively assess patient needs and achieve progress in clinical care for patients with chronic wounds. The secondary purpose is to evaluate the correlation of CWIS scores to different degrees of wound severity by comparison with a validated objective wound grading tool: The Society for Vascular Surgery's (SVS) Wound, Ischaemia, and foot Infection (WIfI) classification system.[8] The hypothesis is that participants with a higher WIfI score experience a poorer HRQoL.

Key Messages

- this article intends to show that the Dutch version of the Cardiff wound impact schedule is a valid and reliable disease-specific instrument to assess the health-related quality of life in patients with chronic wounds of the lower leg
- this instrument can be used as a monitoring tool to assess patient needs and wants in relation to their disease
- the authors believe that it can be beneficial to implement the instrument in the standard care for patients with chronic wounds of the lower leg

2 | MATERIALS AND METHODS

2.1 | Translation of the instrument

The original CWIS instrument was translated following the protocol described in the guidance document "Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes." This guidance document provides a framework for a "language to language" translation process of patient-reported outcomes.[9]

2.2 | Enrolment of participants

Consent of the Medical Ethical Committee of a tertiary academic centre in the Netherlands for conducting this study was obtained. In the period of February 2018 till July 2018, patients with chronic wounds of the lower leg and/or foot were enrolled from the vascular surgery outpatient clinic of the hospital. The number of included participants was based on sample size calculated by a statistician using Cronbach's α.

Exclusion criteria were patients under the age of 18 years, patients with a neurocognitive disorder to the extent that they cannot be expected to fill in the questionnaires adequately, patients who do not master the Dutch language and patients with a traumatic wound. Before enrolment participants received verbal and written information about the nature and aim of the study and how

their personal data would be used and stored. After signing informed consent papers, participants were asked to fill in the Dutch translation of the CWIS and the Rand SF36 under supervision of one of the researchers in a separate room after their visit to the outpatient clinic. All participants were able to complete the questionnaires without help from the supervising researcher.

One week after being enrolled in the study, participants received an invitation via email to fill in the CWIS via an online questionnaire. When participants did not possess an email address, they received the instrument with a return envelope 1 week after being enrolled in the study. Participants were instructed to fill in this second administration within 5 days of receival.

The SVS recently published a lower extremity threatened limb classification system based on WIfI. During the visit of patients to the outpatient clinic, the wound status was also assessed by the researchers using the WIfI classification system.[8] Baseline demographic data were extracted from the electronic health record of a participant after inclusion.

2.3 | Statistical analysis

For statistical analysis, SPSS statistics version 25.0 was used, and a P value of $<.05$ was considered significant.

2.3.1 | Validity

Face validity was evaluated in a short pilot study wherein the first five participants were included. These participants were asked the following questions each time after filling in a subsequent question of the instrument: do you think this question is relevant in relation to your disease? Do you understand this question? *Construct validity* was evaluated by the research group in cooperation with an expert group of several clinicians who treat patients with chronic wounds. *Discriminant validity* was evaluated by analysing the capacity of the instrument to differentiate between participants with a variable 1-year risk of amputation according to the WIfI classification.[8] This capacity was analysed using one-way analysis of variance (ANOVA). *Criterion validity* was evaluated by comparing the domain scores of the CWIS at baseline with the relevant domains of the instrument used in previous validation studies as the gold standard: the SF-36. The correlation between the domains of both instruments was analysed using Spearman's ρ, and reference values were used to evaluate the outcome of each correlation.

2.3.2 | Reliability

The *test-retest reliability* was evaluated by inviting participants to fill in the instrument for a second time 7 days after their inclusion in the study. This was evaluated by calculating the intraclass correlation coefficient (ICC). An ICC of 0.6 was set as the minimal value to achieve acceptable intraclass correlation. The *internal consistency* was evaluated by analysing Cronbach's α coefficient of the scores filled in for the items of all domains at baseline. If Cronbach's α was 0.70 or higher, then internal consistency was deemed acceptable.[10]

3 | RESULTS

Eighty-three patients consented to participate and were included in the study. For the final analysis, two participants were excluded, one participant because of missing data and one participant because of doubts about their cognitive condition. A total of 50 participants filled in the follow-up form of the questionnaire (60% response rate). For all analyses, the data of all 81 participants were used except for the analysis of test–retest reliability. For the analysis of the test–retest reliability, the data of the 50 participants who filled in the form at baseline and at 1-week follow-up were used. Demographics of participants at baseline are depicted in Table 1.

3.1 | Validity

Before enrolling patients for this study, the instrument was assessed by a group consisting of the research group and experts in wound management. These experts were a vascular surgeon, an advanced nurse practitioner in vascular surgery specialised in wound care, and several nurses specialised in wound care. Their judgement of the instrument was positive, therefore *construct validity* was acquired. During the pilot study, no question was deemed irrelevant and all items of the questionnaire were viewed as understandable by participants. *Face validity* was therefore acquired, no changes were made to the instrument. Evaluation of *discriminant validity* is shown in Figure 1. As shown in Figure 1, the mean total CWIS score seems to be lower in groups of participants who have a higher 1-year amputation risk according to the WIfI score, except for the intermediate amputation risk group. This difference was also not significant, significance calculated using one-way ANOVA was .541. Assessment of the correlation between the CWIS instrument and relevant domains of SF36, the gold standard, is shown in Table 2. A significant and moderate to high

TABLE 1 Patient characteristics at baseline

Patient characteristics at baseline	
Characteristic	**Population data (%) (N = 81)**
Mean age (years)	67,33
Gender	
Male	59 (72.8)
Female	22 (27.2)
Mean amount of wounds	1.37
Anatomical distribution of wounds[a]	
Lower leg (including malleoli)	18 (22.2)
Foot	63 (77.8)
Diabetes mellitus	
DM 1	19 (23.5)
DM 2	38 (46.9)
No DM	24 (29.6)
Smoking	
Never	40 (49.4)
Past	23 (28.4)
Current	18 (22.2)
Kidney function	
eGFR<30	8 (9.9)
eGFR 30-60	26 (32.1)
eGFR>60	47 (58.0)

[a]For participants with multiple wounds, the most proximal wound is depicted in these values.

correlation, based on reference correlation,[11,12] between the CWIS instrument and SF36 was calculated for the CWIS domains of physical symptoms, social life, total HRQoL, and in part for the domain well-being. Significance was not shown for the correlation between the CWIS domain well-being and the SF36 domain social functioning. *Criterion validity* was therefore viewed as acceptable.

3.2 | Reliability

As shown in Table 3, the intraclass correlation of the scores at baseline and 1 week after inclusion was higher than 0.6 in all domains except for satisfaction with HRQoL. Acceptable intraclass correlation was therefore achieved and *test–retest reliability* was deemed as good. In Table 4, the internal consistency of the instrument is evaluated using Cronbach's α. In all domains, a value higher than 0.70 was reached, therefore the *internal consistency* of the instrument is evaluated as acceptable.[10]

4 | DISCUSSION

In this study, a Dutch translation of the CWIS instrument is validated for clinical use for patients with chronic lower leg wounds. The CWIS instrument is a disease-specific questionnaire that was developed to measure HRQoL in patient with chronic leg ulcers and diabetic foot ulcers. The importance of measuring the effect of disease on HRQoL is increasingly recognised. Measurement can provide the clinician with information about the functional capacity and well-being of patients in relation to their disease. It can also give an insight on the overall response (eg, psychologically and impairment in daily activities) of a patient to a certain clinical condition. This information can be valuable to assist the clinician in treatment choices in a shared decision manner. It can also provide information that assists policy makers in making policy decisions. The CWIS questionnaire was initially developed in the United Kingdom and has since been translated to multiple languages and was validated in several countries.[11-15] The aim of the developers was to construct an instrument, which would reliably and validly evaluate disease-specific quality of life. Before the CWIS was developed, the quality of life in patients with chronic wounds was merely assessed using generic instruments. A disease-specific instrument is believed to be a better instrument to assess matters of importance for the concerning patient group and the clinicians that treat them.[6]

Our study endorses this belief: all generic domains of the CWIS correlated with relevant domains of the SF36. This moderate to high level of correlation suggests that the instrument can be used as an adjunct to generic instruments to measure HRQoL. Construct validity was evaluated by direct feedback of a part of the research group and an expert panel, overall feedback was positive, and no changes to the instrument were made. Furthermore, as previously also displayed in other CWIS validation studies, the test–retest reliability of the instrument was shown to be excellent and internal consistency of all domains of the instrument was good. The results of the test–retest reliability reinforce the idea that the CWIS can be used as an outcome measurement, also to assess the effects of treatment, in the daily care of patients with chronic wounds. Our study used electronic follow-up forms with the idea that this would positively affect the follow-up rate.

The clinical condition of the lower leg can be assessed by the SVS's WIfI classification system.[8] In our study, a correlation between the mean CWIS score and the 1-year amputation risk according to the WIfI classification system could not be found. This could be a result of the relatively small sample size or the specific classification of the WIfI scoring system. This could also be due to the fact that HRQoL is subjective and multifactorial. In the

TABLE 2 Correlation between domains of CWIS and SF36 compared with reference correlations using Spearman's ρ

Correlation domains of CWIS and SF36				
Domain of CWIS	**Domain of SF36**	**Reference correlation[a]**	**Reference 2[b]**	**Spearman's ρ**
Physical symptoms	Physical functioning	.63	.57	.64**
	Pain	.45	.61	.55**
	Vitality	.49	.47	.63**
Well-being	General health	.53	.47	.26*
	Social functioning	.51	.27	.23*
Social life	Role emotional	.56	.40	.43**
	Social functioning	.64	.77	.53**
	Vitality	.43	.53	.48**
Total HRQoL	Mental health	.47	.66	.54**
	Physical functioning	.57	.41	.46**
	Role emotional	.47	.34	.42**
	Vitality	.43	.69	.57**

Note: *Correlation is significant at the .05 level. **Correlation is significant at the .01 level.
[a]Values as shown in Reference 11.
[b]Values as shown in Reference 12.

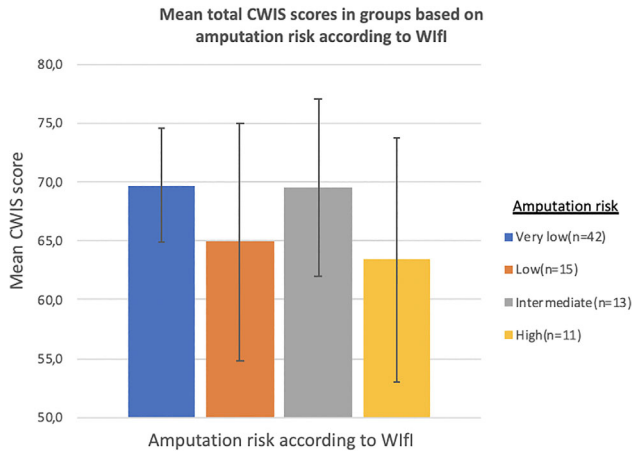

FIGURE 1 Mean total CWIS score in groups based on amputation risk according to WIfI. CWIS, Cardiff wound impact schedule; WIfI, Wound, Ischaemia, and foot Infection

present study, patients with the same WIfI score can experience a strongly different HRQoL as measured by the CWIS. It is known that a person's expectations regarding health and their capacity to cope with limitations and disability can affect their perception of health and satisfaction with life in a great way.[16] Pain may also play an important role in our study population, since it consisted of patients with chronic wounds of different aetiologies. The WIfI classification does not evaluate pain, while pain can have a substantial negative impact on the quality of life.[17]

Limitations of this study were the study population that mostly consisted of male participants, the relatively small sample size, and the fact that the study was only performed in one medical centre. Also, a limitation of the CWIS instrument in general mentioned in an earlier validation study is that participants reflected negatively on the amount of questions in the questionnaire. Our belief is that a shorter questionnaire will lead to an increased

TABLE 3 Intraclass correlation at baseline and 1-week follow-up, test-retest reliability

Intraclass correlation domains of CWIS at baseline and 1 week after inclusion	
Domain of CWIS	**ICC**
Physical symptoms	.868*
Well-being	.810*
Social life	.722*
HRQoL	.713*
Satisfaction with HRQoL	.566*

Note: *Correlation is significant at the .01 level.

TABLE 4 Internal consistency of domains of CWIS evaluated using Cronbach's α

Internal consistency of domains of CWIS	
Domain of CWIS	**Cronbach's α**
Physical symptoms	.921
Well-being	.780
Social life	.928

follow-up rate, increased participant satisfaction, and would be more suitable to implement into standard clinical care.

5 | CONCLUSION

Our Dutch CWIS is a valid and reliable disease-specific instrument to assess HRQoL in patients with chronic wounds of the lower leg irrespective of aetiology. It can be used as a monitoring tool to better assess patient needs and wants in relation to their disease. It can hopefully also provide solid data for further research. Preferably a shorter version of the instrument should be developed before implementation in standard clinical care.

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CONFLICT OF INTEREST

The authors declare no potential conflict of interest.

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