Research Article

Validation of Sinhala Version of Cardiff Wound Impact Schedule in Patients with Diabetic Leg and Foot Ulcers

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S U M M A R Y

Purpose: To validate the Cardiff Wound Impact Schedule (CWIS) to assess the health-related quality of life (HRQoL) of Sri Lankan patients with diabetic leg and foot ulcers.
Methods: English version of CWIS was examined for cultural compatibility, translated into Sinhala and pretested. The Sinhala version was administered in parallel with the validated Sinhala version of SF-36 by an interviewer to all patients ($n = 140$) at baseline to determine the construct validity. Reliability of CWIS was measured by internal consistency and test-retest stability. The instrument was readministered in 2 weeks on 33 patients with nonhealing ulcers to determine the test-retest stability and in 3 months on 50 patients with healed ulcers to determine the ability of CWIS to discriminate HRQoL between patients with healed versus nonhealed ulcers. Acceptability of CWIS was assessed by the response rate, completion rate and the average time taken to complete a single interview.
Results: The construct validity demonstrated moderately significant correlations between related sub-scales of CWIS and SF-36 (Spearman's $r = .32−.51$, $p = .021$ to $p < .001$) for the whole study sample. Internal consistencies (Cronbach $\alpha = .68−.86$) and test-retest stability ($.56−.70$) were acceptable. The tool was sensitive in discriminating the impact of the wound on HRQoL in healed versus nonhealed status ($p \leq .001$). The tool showed good acceptability.
Conclusions: The Sinhala version of CWIS is valid, reliable and acceptable for assessing the impact of wound on HRQoL. This instrument is sensitive in detecting the differences of the impact of healed and nonhealed ulcers on QoL in patients with diabetic leg and foot ulcer.

Introduction

Sri Lanka is a South Asian country with a high prevalence of diabetes mellitus rising to epidemic levels [1]. Diabetic foot ulcer disease is a common complication of diabetes mellitus which is associated with a high rate of morbidity [2]. Some ulcers progress to chronic stage due to various pathological reasons. Both the wound and the treatment for the wound have a significant impact on the daily living of these patients. Restricted mobility, pain, exudate and odor, hamper the quality of living [3], while increased family tensions, social isolation and restrictions in employment further

exaggerate the negative influences of the wounds on these patients [4]. Furthermore, the patients suffer from emotional stress due to fear of recurrence of ulceration, repeated bouts of infection and potential life-long morbidity [5]. Many investigators have shown that patients with active diabetic foot ulcers were more depressed [6] and had poorer health related quality of life (HRQoL) than did the general population [7], those with diabetes without ulcers [8,9] and those who had successful minor amputations [10]. Hence, consequences of ulcers are shown to affect physical, psychological, social and financial [11] aspects of the individual leading to poor quality of life (QoL) [12,13].

The terms "QoL" and "HRQoL" are used interchangeably by researchers. It is a complex concept with multiple dimensions [14,15]. HRQoL is a subjective assessment of an individual's physical and psychological well-being which denotes how a specific disease or intervention has impacted a patient's life [10]. Measuring the

HRQoL is useful in clinical practice, in research and in assessing quality improvement and assurance [15]. Measuring HRQoL in clinical practice provides important information that supports the clinician to extend more individualized care for the patient [15]. With the identification of QoL as an important aspect in patient care, there is growing interest in using HRQoL as a routine outcome measure in healthcare [15]. If measuring HRQoL is planned in future routine nursing interventions, it is vital that valid, reliable and acceptable tools are available [14,16].

Although a number of generic tools such as Short Form Health Survey-36 (SF-36) [17], EuroQOL five dimension questionnaire [13,18] and the Nottingham Health Profile [19] have being used to assess HRQoL of patients with ulcers, they only assess QoL in general terms and are not designed to detect the impact of the ulcer on the individual [4,14]. To overcome this issue, disease specific instruments have being developed with more focus on specific disease characteristics and the impact of these on physical, emotional and social health [11]. One such instrument is the Cardiff Wound Impact Schedule (CWIS) which was developed and validated by the Wound Healing Research Unit in Cardiff at the University of Wales, College of Medicine to investigate the impact of lower leg chronic wounds on HRQoL [20]. Validity of CWIS in assessing wound specific HRQoL has been established by its authors and by other researchers who have used it subsequently. Price and Harding [20] who authored the CWIS have demonstrated its construct validity by showing moderate significant correlations between related subscales of CWIS and SF-36. It is also shown to have a high internal consistency and good reproducibility. The CWIS has been subsequently translated into German, French and US English to facilitate wider use [21]. Recently, a Canadian study [22] has validated the CWIS and confirmed its validity to differentiate the HRQoL between healed and nonhealed diabetic foot ulcer states. Most recently, the validated Chinese version of CWIS has shown a strong correlation with SF-36, a high internal consistency and an ability to identify differences in HRQoL with changes in ulcer severity [23].

Assessing HRQoL in patients with diabetic leg and foot ulcers enables the healthcare providers to get an insight into the impact of the wound on the patient. Such an understanding is vital in making decisions about treatment options, managing compliance [24] and patient welfare. Absence of a locally validated wound-specific tool to assess QoL has precluded the health professionals in Sri Lanka in extending such care to patients with diabetic leg and foot ulcers. HRQoL is suggested as an important component which could be included in future foot care programs, thus requiring the need of a tool. Among the wound specific tools available, CWIS was considered the most suitable, considering its proven validity and its focus. Therefore, the aim of this study was to validate the Sinhala version of CWIS to assess HRQoL of Sri Lankan patients with diabetic leg and foot ulcers.

Methods

Study design

This was a descriptive cross-sectional study that evaluated the construct validity, reliability, ability to discriminate HRQoL between healed versus nonhealed status and acceptability of the Sinhala version of CWIS. Data for this study was collected from June to December 2014 by the principal investigator.

Setting and sample

The study was conducted at the Colombo North Teaching Hospital, Ragama. The sample size to assess the construct validity of the instrument was estimated based on the assumption that the number of observations needed is 5–10 times the number of variables (items) in the instrument [25]. Accordingly, the calculated sample size was 140. Eight additional patients were included to account for possible nonresponses, thus making the final sample size 148. Adult diabetic leg and foot ulcer patients with wound duration of more than 2 weeks but hospitalized for less than 24 hours were eligible to take part in the study. Those who were acutely ill and those with cognitive impairment were excluded from the study. The principal investigator visited the surgical wards daily and invited the newly admitted eligible patients to participate in the study. To assess the test-retest stability of the instrument, the instrument was readministered to a subsample of 35 patients (1/4 of total sample) 2 weeks after the baseline assessment. Of the total 35 patients invited, 33 agreed to participate. To test the ability of the instrument in discriminating the HRQoL in healed versus nonhealed status, the instrument was readministered 3 months after the baseline assessment to individuals who had healed ulcers. The ulcers were healed in 50 individuals out of the total sample of 140.

Ethical considerations

Ethical approval was obtained from the Ethics Review Committee of the University of Sri Jayewardenepura and permission to recruit patients was obtained by the hospital authorities. The instrument was used with the approval of the original authors of CWIS. Patients participated voluntarily for the study and written informed consent was obtained prior to participation.

Measurements

Baseline characteristics
Baseline characteristics of the participants obtained were age, gender, level of education, self-reported visual impairment, diabetes mellitus duration, ulcer duration and ulcer site.

CWIS
CWIS has been designed as a self-administered instrument which inquires into aspects of QoL during a period of 1 week preceding the time of inquiry. It consists of 45 items divided into three subscales, namely, physical symptoms and daily living (PSDL), social life (SL), and well-being (WB). The subscale PSDL comprises 12 items and, SL and WB have 7 items each. The scores are derived from summating the scores obtained on a 5-point Likert scale for each of the three subscales. For PSDL and SL, the items are rated for the extent of the experience during the past week and how stressful that experience was, on an item-by-item basis. The WB scale is rated for response options varying from *strongly agree* to *strongly disagree*. In addition, two specific subscales, mobility and its associated stress (MAS) and, pain and its associated stress (PAS) were identified by considering the relevant items for mobility and pain in the subscale PSDL [20]. All scales are then transformed onto a 0–100 scale using a specific formula [20] that creates an index varying from 0 to 100 where high and low scores indicate good and poor HRQoL respectively. In addition, there are two items measured on a 10-point scale which assess the overall QoL during the preceding week. In accordance with previous studies [20,22,26], the generic instrument SF-36 was used as the gold standard [10] in validating the CWIS.

SF-36
The SF-36 questionnaire comprises of 36 items that are grouped to eight conceptual subscales, namely, physical functioning, role limitations-physical, bodily pain, general health, vitality, social functioning, role limitation-emotional and mental health. The score

of each subscale is computed onto a scale of 0-100 where a high score denotes high quality of life and vice versa.

Cultural compatibility and translation. The first step in the present validation study was to assess the CWIS for its suitability to the local setting. Once the research group assessed and confirmed the cultural compatibility, the English version of the instrument was translated independently to Sinhala by two translators who are fluent in both languages. The two translations were later compared and differences were discussed and adjusted with the consensus from both translators. The adjusted Sinhala version of CWIS was back translated by a third translator to ensure that the language is a correct translation of the original [27,28]. The research team decided to use the CWIS as an interviewer administered instrument, considering the wide variation in education level among the patients and the difficulties (limited sight, pain, discomfort) the patients would encounter in completing it as a self-administered instrument in the hospital setting.

Pretest. As pretesting of an instrument helps to identify and solve potential problems in its administration [28], translated questionnaire was pretested among 10 patients with diabetic leg and foot ulcer in surgical wards of the District General Hospital in Negombo, a location away from the setting of the validation study. Administration of each questionnaire in the pretest was followed by a structured interview with the patient. The interview was directed to each item to determine whether the wording is confusing, difficult to understand, difficult to answer, upsetting or offensive and/or to obtain suggestions from participants to ask the questions in a better way. Few words were modified following the pretest.

Face validity. The face validity of the translated, pretested CWIS was assessed by a group of experts in clinical research who examined the relevance of each item of the instrument in assessing the impact of the wound on patient's life and also the adequacy of the instrument to cover all relevant areas in HRQoL of patients with diabetic foot and leg ulcers.

Construct validity. In this study, the construct validity was assessed by correlating the scores of subscales of CWIS with corresponding subscales of SF-36 validated to be used among Sri Lankans [29]. Identification of related subscales of CWIS and SF-36 was based on the validation study conducted by the original authors of the CWIS [20] and other validation studies using SF-36 to assess the construct validity of CWIS [23,26]. Accordingly, the subscales PSDL, SL and WB in CWIS were considered as corresponding to the subscales physical functioning, social functioning and role limitation (physical), and mental health and role limitation (emotional) of SF-36 respectively. In addition, specific subscales, MAS and PAS in CWIS were correlated with corresponding subscales of SF-36 [20]. In addition to the data of the total sample ($n = 140$), grouped data based on gender (male vs. female), age (≤ 50 vs. > 50 years) and wound duration (≤ 6 vs. > 6 weeks) were compared separately to examine the validity of the instrument across different groups. The strength of the correlation, *r* with a range of .30−.49 and .50−1.0 were considered medium and large respectively [16]. However, as per the previous research findings, the relationship was expected to be moderate and positive [20,26].

Discriminant validity. The ability of CWIS to discriminate the HRQoL of patients with healed verses nonhealed ulcers was determined in the subsample of 50 patients in whom the ulcers were healed in an interval of 3 months. The scores obtained in healed status were compared with those at baseline when the ulcers were active.

Reliability. Reliability was measured by internal consistency and test-retest stability. Internal consistency was assessed using Cronbach α coefficients, where values ≥ .70 were considered acceptable. Test-retest stability was assessed by intraclass correlation coefficients (ICC) calculated by administering the CWIS to a subsample of 33 patients with nonhealing ulcers in an interval of 2 weeks from the baseline assessment. ICC > .60 was considered acceptable [26].

Acceptability. The acceptability was assessed by the response rate, the rate of completion of scales and items and the average time taken to complete a single interview.

Data analysis

Descriptive statistics were used to present baseline characteristics of the patients. As scores of CWIS and SF-36 were not normally distributed, nonparametric Spearman's correlation coefficient test was performed to assess the construct validity of CWIS [26]. The ability of CWIS to discriminate the impact of healed versus nonhealed status on HRQoL was determined by paired *t* test. Reliability of the instrument was determined by Cronbach α coefficients and ICC. All tests were performed using SPSS version 21 (IBM Corp., Armonk, NY, USA). Level of significance was accepted at $p < .05$.

Results

Characteristics of participants

Characteristics of the total sample and subsamples are presented in Table 1. A total of 140 patients participated in the study. Of these, 51.0% ($n = 71$) were males. The mean age of the participants was 58.24 years ($\pm$ 10.02 years). The mean duration of diabetes mellitus was 9.59 years ($\pm$ 8.51 years). Lastly, 51 patients (36.7%) had impaired near vision based on self-reports.

Table 1 *Characteristics of Total Sample at Baseline and Subsamples at Subsequent Assessments.*

Variables	Categories	Baseline assessment[a] $n = 140$	Second assessment[b] $n = 33$	Third assessment[c] $n = 50$
		n (%)	*n* (%)	*n* (%)
Age (yr)	≤ 50	31 (22.1)	13 (39.4)	14 (28.0)
	> 50	109 (77.9)	20 (60.6)	36 (72.0)
Gender	Male	71 (50.7)	19 (57.6)	31 (62.0)
	Female	69 (49.3)	14 (42.4)	19 (38.0)
Education	No formal education	5 (3.6)	1 (3.0)	2 (4.0)
	Up to ordinary level	74 (54.0)	18 (54.5)	21 (42.0)
	Up to advance level	51 (37.2)	14 (42.4)	22 (44.0)
	Tertiary education	7 (5.1)	0 (0.0)	5 (10.0)
DM duration (yr)	≤ 10	87 (63.5)	19 (57.6)	31 (62.0)
	> 10	50 (36.5)	14 (42.4)	19 (38.0)
Ulcer site	Foot	114 (81.4)	28 (84.8)	40 (80.0)
	Leg	26 (18.6)	5 (15.2)	10 (20.0)
Ulcer duration (wk)	≤ 6	106 (75.7)	20 (60.6)	41 (82.0)
	> 6	34 (24.3)	13 (39.4)	9 (18.0)

Note. DM = diabetes mellitus.
[a] Total sample considered to evaluate construct validity of the instrument.
[b] Subsample considered to evaluate test-retest stability of the instrument.
[c] Subsample considered to evaluate discriminant validity of the instrument.

Table 2 Correlation of Corresponding Subscales of CWIS and SF-36 (N = 140).

CWIS subscale	SF-36 subscale	Spearman's r	p
PSDL	PF	.41	< .001
SL	SF	.40	< .001
	RLP	.38	< .001
WB	MH	.32	< .001
	RLE	.19	.021
MAS	PF	.51	< .001
PAS	BP	.36	< .001

Note. BP = bodily pain; CWIS = Cardiff Wound Impact Schedule; MAS = mobility and associated stress; MH = mental health; PAS = pain and associated stress; PF = physical functioning; PSDL = physical symptoms and daily living; RLE = role limitation emotional; RLP = role limitation physical; SF = social functioning; SF-36 = short form-36; SL = social life; WB = well-being.

Validity

The results of the construct validity of the instrument assessed by correlating subscales of CWIS with corresponding subscales of SF-36 are shown in Table 2. Correlations were moderate and positive ($r = .32-.51$) in at least one subscale of the SF-36 for all subscales of CWIS. All correlations except for one were highly significant ($p \leq .001$).

The correlations between the two instruments assessed across subgroups of gender (male vs. female), age (≤ 50 vs. > 50 years) and wound duration (≤ 6 vs. > 6 weeks) are shown in Table 3. All associations except the correlations between subscale WB (CWIS) and the corresponding subscales of SF-36 were moderate to high ($r = .32-.59$) and significant ($p = .044$ to $p < .001$), even when the data was disaggregated.

The ability of CWIS to discriminate the impact of healed versus non-healed status of wounds on HRQoL is shown in Table 4. HRQoL in healed status had significantly higher ($p < .001$) scores than those in nonhealed status across all three subscales of CWIS.

Reliability

Internal consistency measured for the CWIS was found to be good (Cronbach $\alpha = .89$) and it was equally high in two of the three subscales (Cronbach α of .86 for PDSL and .79 for SL). Cronbach α was .68 for subscale WB. The test-retest stability evaluated using ICC was acceptable for subscales PSDL (.65) and SL (.70). However, the value obtained for WB was poor (.56).

Acceptability

The response rate was 94.5% and the completion rate was 100.0%. Mean time taken to complete one interview was 15.55 (± 3.97) minutes.

Table 4 Discrimination of HRQoL with Status of Wound.

CWIS subscale	Healed (n = 50) Mean ± SD	Nonhealed (n = 50) Mean ± SD	p
PSDL	67.28 ± 8.37	36.07 ± 18.22	< .001
SL	58.45 ± 16.00	31.57 ± 18.06	< .001
WB	64.28 ± 23.66	29.33 ± 25.41	< .001

Note. CWIS = Cardiff Wound Impact Schedule; HRQoL = health related quality of life; PSDL = physical symptoms and daily living; SL = social life; WB = well-being.

Discussion

The present study was conducted to validate the wound specific Sinhala version of CWIS to assess the impact of diabetic leg and foot ulcers on the HRQoL of patients in Sri Lanka. Previous studies on validating CWIS had mainly chosen the self-administration mode [20,26]. In the present study, the CWIS was administered using an interviewer mainly considering the wide variation in literacy among Sri Lankan patients. This is acceptable as the authors of CWIS have suggested that the mode of administration can be selected based on the contextual features of the setting [20].

The culturally acceptable Sinhala version of CWIS demonstrated acceptable construct validity with corresponding subscales of the generic tool SF-36, previously validated in a Sri Lankan setting. Moderate and significant correlations were shown for the subscales PSDL and SL, while showing a slightly lower but significant correlation for WB. The validity of the original version of CWIS [20], and the subsequently translated versions of it [22,23,26] have also been assessed by appraising the construct validity against SF-36 which showed moderate to strong correlations. Present study adopted a unique further step of assessing the validity of CWIS across age groups, gender and the duration of the wound, and the patterns of correlation were similar to that of the whole study sample.

Reliability measured through internal consistency showed good and acceptable results for PSDL and SL. This finding is agreeable with a Chinese study that validated the CWIS tool, demonstrating a high internal consistency for all subscales with Cronbach α ranging from .78 to .92 [23]. Although WB showed a lower internal consistency, this value was considered acceptable, since the scale comprised of a small number of items [16]. In the present study, the test-retest stability of the instrument showed acceptable results for PSDL and SL. Test-retest stability value for WB was poor and was slightly lower than the acceptable level of .60. It is reported that scales designed to measure mood states is less likely to remain constant over time, giving low values for test-retest reliability [16]. This may be a reason for low ICC values

Table 3 Correlation of Corresponding Subscales of CWIS and SF-36 across Subgroups (N = 140).

CWIS	SF-36	Gender				Age (yr)				Wound duration (wk)			
		Male (n = 71)		Female (n = 69)		≤ 50 (n = 31)		> 50 (n = 109)		≤ 6 (n = 106)		> 6 (n = 34)	
		r	p	r	p	r	p	r	p	r	p	r	p
PSDL	PF	.42	< .001	.34	.005	.50	.003	.41	< .001	.46	< .001	.34	.044
SL	SF	.41	< .001	.32	.008	.39	.023	.38	< .001	.40	< .001	.32	.060
	RLP	.38	.001	.44	< .001	.40	.021	.42	< .001	.44	< .001	.33	.054
WB	MH	.19	.113	.34	.004	.28	.113	.28	.003	.28	.003	.25	.138
	RLE	.27	.026	.19	.115	.20	.045	.16	.112	.17	.073	.22	.200
MAS	PF	.59	< .001	.36	.003	.50	.003	.50	< .001	.51	< .001	.48	.003
PAS	BP	.50	.009	.39	< .001	.27	.132	.38	< .001	.36	< .001	.36	.031

Note. BP = bodily pain; CWIS = Cardiff Wound Impact Schedule; MAS = mobility and associated stress; MH = mental health; PAS = pain and associated stress; PF = physical functioning; PSDL = physical symptoms and daily living; RLE = role limitation emotional; RLP = role limitation physical; SF = social functioning; SF-36 = short form-36; SL = social life; WB = well-being.

obtained in the present study for the scale WB in which the items assess the perception.

The Sinhala version of CWIS was sensitive in detecting differences in HRQoL with the state of the wound. The scores obtained for all three subscales were significantly higher ($< .001$) when the wounds healed, when compared to the unhealed status. These findings are agreeable with the findings of the validation study of the original version of CWIS [20] and the Canadian study [22]. The Chinese study [23] had also demonstrated the ability of CWIS in detecting the impact of the wound on HRQoL based on different etiologies of ulcer and ulcer severity. This aspect of validity was not assessed in the present study. High acceptability of the CWIS denoted by high response rate (94.5%), high completion rate (100.0%) and an acceptable time taken to complete may be attributed to collection of data through an interviewer [30].

There are some limitations in this study. Patient recruitment was done in a single hospital where the characteristics of the patients are somewhat similar. This would prevent generalizing the results and the use of the questionnaire nationwide. In the present study, only healed versus nonhealed status was considered in assessing the discriminant validity. Sensitivity of the instrument would have being improved further, if other characteristics such as ulcer severity which has an impact on the HRQoL were included. Furthermore, the study was limited to patients with diabetic leg and foot ulcers. A future study aimed at chronic ulcer patients with different etiologies will improve the validity of the instrument and its wider use.

In conclusion, the Sinhala version of CWIS is a valid, reliable and acceptable research instrument for assessing the impact of wound on HRQoL among diabetic patients with leg and foot ulcers. The Sinhala version of CWIS was also found to be valid in assessing the impact of the wound on HRQoL across all ages, in both gender and wounds of varying durations. It is also sensitive in detecting the differences of the impact of healed and nonhealed wounds on QoL in diabetic foot ulcer patients. The authors recommend that health professionals use the validated Sinhala version of CWIS to identify the Sri Lankan patients with an adverse impact of the wound on the HRQoL and give due consideration to improving their QoL when making decisions about management.

Conflicts of Interest

The authors declare no conflicts of interest.

Acknowledgments

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