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Research Article

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

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SUMMARY

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 subscales of CWIS and SF-36 (Spearman's $\rho = .32-.51$, $p = .021$ 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.

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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

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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 been 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 been 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 ($r = .22-.56, p = .010$ to $p < .001$). It is also shown to have a high internal consistency (Cronbach $\alpha = .77-.96$) and good reproducibility ($r = .86-.93, p < .001$). 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 ($r = .79, p < .010$), a high internal consistency (Cronbach $\alpha = .79-.93$) and an ability to identify differences in HRQoL with changes in ulcer severity ($p < .010$) [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 summing 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*. All three 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.

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

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