ORIGINAL ARTICLE

Development and Validation of Discomfort Evaluation of Wound Instrument (DEWI) in Patients With Diabetic Foot Ulcers

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ABSTRACT

Introduction: Discomfort is the most common complaint by patients with a chronic wound, especially patients with diabetic foot ulcers. However, in a clinical setting, discomfort receive less attention and poorly understood. To date, no validated instrument specific to measure discomfort in a chronic wound. The aimed of this study was to develop and validate a newly instrument measured discomfort in patients with a chronic wound. **Methods:** Items were developed through literature review and refining by an expert. A psychometric evaluation of the instrument was conducted using confirmatory factor analysis and construct validity with convergent and discriminant validity. Of 140 patients with diabetic foot ulcers completed the final instrument at three general hospitals in Jakarta, Indonesia. **Results:** A total of 11 items was reported valid according to the confirmatory validity test. Factor loading ranges from 0.357 to 0.658. Convergent and discriminant validity of the DEWI scale reported good. **Conclusion:** A 11-items psychometrically sound measure of comfort in patients with diabetic foot ulcers. This tool will be therapeutically useful in providing a structured technique to evaluate the level of comfort of wound care.

Keywords: Discomfort, Diabetic Foot Ulcer, Wound Care, Psychometric, Validation

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INTRODUCTION

Chronic woundspose a significant challenge due to its high prevalence and complexity of the healing process. Diabetic foot ulcers (DFUs)are the most common chronic wound, accounted for nearly 50% of hospitalization and 85% of all significant amputation in patients with diabetes (1,2). As resultsof the amputation, nearly half of patients either die or lose their extremities within five years (3). Holistic management including comprehensive assessment and adequate treatment may save limbs, potentially to save a life, and improve quality of life (4). Unfortunately, despite the evidence, suggested that physiological aspect including comfort care is essential element accelerates wound healing process, comfort care receives less attention and poorly understood in clinical practice (5–7). Comfort isconsidered as a state of ease,relief, and transcendence in fouraspectsincludingphysical, psychosocial, sociocultural, and environmental (8). Pain is reported as the most common complaint in patients with DFUs, resulting to persistent discomfort, daily activities disturbance, sleep disturbance, and reduced satisfaction to treatment (9). A previous longitudinal study found that severe pain associated with worsening depression symptoms (10). Emerging evidence suggests that psychological and behavioral factors may play an essential role in the management of DFUs (10). Addressing discomfort in patients with DFUs would help advance knowledge on DFUs care management.

To date perceive of discomfort has been measured explicitly by asking the participant to rate discomfort through an open-ended question or using a general scale such as the modified perceived comfort scale (11,12).

(13) has been developed a questionnaire to measure comfort in a general context, among patients in the perioperative room, patients undergoing radiation, and in the hospice ward. To our knowledge, a comprehensive questionnaire has not been published that can reliably measure discomfort in patients with DFUs.The aimed of this study was to develop and initially validate the Discomfort Evaluation of WoundInstrument (DEWI), a new instrument used to measure the discomfort in patients with DFUs. To accomplish this, the psychometric properties of DEWI were examined, including content validity, and construct validity.

Background and conceptual framework

Somei nstruments that examine psychosocial aspects already exist, but most of these instruments are still general not spesific to measure comfort. The most common instrument used tomeasure the psychosocial aspects were life quality measurements such as the Nottingham Health Profile (NHP) instrument (14), European Quality of life (15) and the Health Form Short Study 36 Health Survey (SF-36) (16) and Skindex-29 (17). (18) states that general measurement tools are not effective andless sensitive to measure thei mpact of wound care on patient's comfort. Further, (18) developed a specia quality of life measurement tool for patients with leg vein ulcers called VLU-QoL (The Venous leg ulcer quality of life). In addition, specific instruments was developed by the Wound healing Research Unit The University of Wales College of Medicine to measure impact of chronic wounds on quality of life, namely the Cardiff Wound Impact Questionnaire. However, these instruments have not specifically measured comfort in chronic wound patients.

(13) states that comfort is the immediate state of reinforcement through the fulfillment of human needs for relief (ease), ease (calm), transcendence (transcendence) in four contexts of experience (physical, psychospiritual, sociocultural, and environmental). Relief is a state of relief from discomfort or individual conditions that have reached their needs. For example, patients complained pain and they receive a pain killer or relaxation theray, then they may fill comfort after their pain relief. Ease is the absence of specific inconveniences or an individual's condition of calm and achieving satisfaction.Transcendence is the ability to increase comfort over discomfort when an individual cannot eliminate it or avoid it or a condition where the individual is able to adapt.

MATERIALS AND METHODS

Instrument development

To begin the instrument development process, a relevant literature search was examined to generate a list of items that reflect discomfort in patients with DFUs. The aim of the review article was to identify how discomfort has been conceived in similar research and to focus on areas where the existing discomfort scale could be improved. Based on their examination of the literature, the authors decided to utilize a conceptual framework of describing discomfort in DFU patients, with dimensions ranging into the three major conceptual areas of pain, sleep disturbance, and everyday activities. An interactive process based on content expert/user feedback and pilot testing was used to assess each item's readability and comprehension.

Establishing psychometric properties

Content validity

A completed instrument was given to a six expert comprise two experts in medical-surgical nursing and wound care, and one expert in mental health nursing, endocrinology, public health, psychiatric, and one expert in instrument development. A Delphi method was used to obtain the content validity index (CVI). This expert was asked to review each item and provide feedback in three aspects:1) Relevancy, using a low to high (1 to 4), experts asked to rate how relevance each item are to filtering discomfort in patients with DFUs. 2) Clarity, evaluate each item for clarity, ambiguity, and conciseness; and (3) Content omission, experts were asked to identify any characteristics that have not been recognized by the included items (DeVellis, 2003).

Confirmatory Factors Analysis and Construct Validity

The aim of confirmatory validity was to assess the stability of the factor structure and further analyse its reliability and validity by administering the newly designed instrument to an independent sample. A cross-s ectional study was conducted to patients with DFUs in three referral hospital located in Jakarta, Indonesia. A total of 140 patients were included in this study. Inform consent was obtained before study. Subjects were informed a form that included the newly designed Discomfort Evaluation of Wound Instrument (DEWI) as well as the Depression Anxiety Stress Scales (DASS). Specifically, DEWI and Cardiff Wound Impact (CWI) were included to test for convergent and discriminant validity using Pearson's coefficients.

Ethic Clearance

The Health Research Ethics Committee of an affiliated university provided ethical approval for this study (reference No. G.3/019/KEPK-UI/II/2019).

RESULTS

Items development

To accurately depict discomfort evaluation in a chronic wound, 30 questions were developed using existing scales and studies, as well as novel ones. Of the questionswere taken directly from extantof the concept of comfort from Kolcaba (2003) including three types of comfort (relief, ease, and transcendence) in the fourth dimension (physical, psych spiritual,

environmental, and sociocultural). Secondly, the instrument consist of three part: 1). A total of 15 items of demographic characteristics. 2) comfort level that consists of 27 items. 3) Three items of type of discomfort. Thirdly, Because this instrument was meant to quantify discomfort, a numeric rating scale ranging from 0 to 10 selected as the optimal item answer type. The researcher endeavored to generate statements withclarity, relevance, and appropriateness, this was validated by expert consultation (details below). Fourth, item wording was carefully reviewed based on literature insights to design a scale suitable to describe discomfort in a chronic wound. Fifthly, cognitive testing was conducted to 47 patients with DFUs and reported that all items question were understandable and clear.

Content validity

The original item pool was assessed by six specialists, including a faculty member with competence in medical-surgical nursing, mental health nursing, endocrinology, psychiatry, public health, and statistician. Every assessor has been rated objects based on their relevancy, clarity, and lack of information. The primary researcher revises item working based on written and verbal feedback from each expert after the first round of expert consultation.The content validity index for relevance was 0.83, and for the clarity, aspect was 0.83.

Confirmatory factors analysis (CFA)

The researchers next performed a confirmatory factors analysis to test the stability of the modified scale's factorstructure. After the CFA test of 30 items of DEWI instruments, 11 items were declared valid, with results of$I2$ was 64.05, df = 44, the p-value was 0.025. The chi-square test showed significant results which means the model is not fit with the data. However, the Root Mean Square Error of Approximation (RMSEA) value was 0.057 was obtained with probability ≤ 0.05 being 0.086, means that the model is fit with data The factor load of each item ranges from 0.357 to 0.658 (Figure 1).

Tabel I : Convergen and discriminant validity between Discomfort Evaluation of Wound Instrument and *Cardiff Wound Impact* (n=115)

Validity	Correlation Coeficient	p-value
Convergent		
Physical discomfort		
Pain	0.579	0.001
Exudate	0.351	0.001
Bad smell	0.407	0.001
Immobilization	0.412	0.001
Psychological discomfort		
Frustration	0.510	0.000
Anxiety	0.571	0.000
Discriminant		
Perseption of discomfort		
Quality of life	0.028	0.771
Life satisfaction	0.030	0.754
Wound severity		
Quality of life	-0.103	0.274
Life satisfaction	0.009	0.924

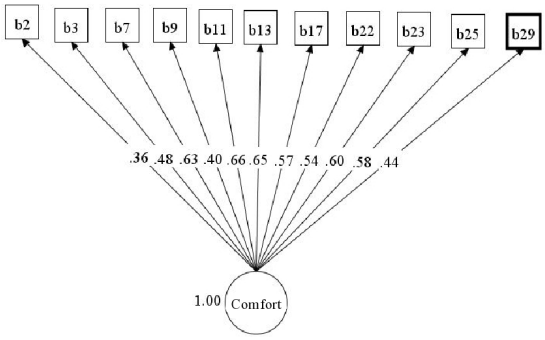

Figure 1. CFA model of discomfort evaluation of wound instrument

Figure 1 : CFA model of discomfort evaluation of wound instrument.

Construct validity

To assess the converging accuracy of the developed scale, Pearson correlation was used to explore the relationship between DEWI and a previously validated instrument, namely Cardiff wound impact (CWI). The study found that DEWI showed a strong relationship with CWI, particularly in the item of pain, itching, exudate, odor, and immobility (physical discomfort), while the psychological domain wasfrustration and anxiety. The correlation coefficient between the two instruments was reported good (>0.3).

Discriminant validity test of DEWI was evaluated by comparing the two instrument with an instrument that theoretically unrelated,namely quality of life and life satisfaction. It was expected that both the items of general discomfort and wound severity were expressed differently from the items of quality and life satisfaction. These results suggest that measurement of discomfort is indeed a different measurement with quality of life or life satisfaction.

DISCUSSION

Throughout this research, a new device for measuring comfort in patients with chronic wounds was devised. The validity of the DWI was assessed using a psychometric exam. In this sample, the study revealed evidence of validity. The resulting tool, based on the analyses, has 11 questions with three subscales, physical and psychological discomfort, and immobilisation, all of which are acceptable. Individual subscales can be graded as follows. The DEWI has 11 elements with scores ranging from 0 (never) to 10 (always); it has a scoring range of 0-110. More research is needed to test the new instrument in larger cohorts to determine normative values and to identify barriers and facilitators to employing DEWI in practise settings. Future research could also be done to define cut-scores, such as levels on subscales at which people are likely to be uncomfortable. DEWI was examined for generalizability in three public hospitals in Indonesia. More testing should be done utilising test-retest procedures to examine the consistency of scores across time. This study was also constrained by a small-to-modest sample size, which prevented the investigation of construct validity and the administration of another psychometric test. Alternative techniques to support construct validity should be investigated further in future study. To date, no psychometrically validated instrument for measuring discomfort in patients with chronic wounds has been developed. In this work, we created and tested a new instrument, the DEWI, to assess physical and psychological comfort and its impact on daily life.

CONCLUSION

The above data isseful since it gives a structured method for assessing comfort level of wound care. Feedback from this instrument may assist uncover strategies to improve comfort in patients with chronic wounds as new instruments are developed.

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