Research Report

COMPOSITE DISTRESS PROFILE: DEVELOPMENT OF A STANDARDISED MEASURE FOR QUANTIFICATION OF MULTIDIMENSIONAL DISTRESS FACED BY PATIENTS WITH DIABETIC FOOT ULCER

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ABSTRACT

Background: Biobehavioural distress is comorbid in most chronic health conditions. Currently, there is a void of a standardised tool which measures distress faced by chronic diabetic foot ulcer patients.

Aims: To develop a new scale for measuring composite distress and to examine its psychometric properties.

Methods: Composite Distress Profile (CDP), a questionnaire to assess composite distress in patients with diabetic foot ulcer, was developed using inputs from 11 patients with the condition. Content validity was ensured by incorporating suggestions from nine experts. CDP was then applied to 60 patients with diabetic foot ulcer twice at an interval of two weeks. Construct validity of CDP was examined by doing contrasted groups approach using WHO BREF-QOL. Criterion validity was examined by doing correlation with scores in SUBI (Subjective wellbeing inventory). Reliability was computed by test-retest reliability.

Results: The final CDP scale has 50-items in a five-domain structure. CDP scores negatively correlated with SUBI. Overall and domain wise test–retest reliability computed using Pearson's product moment correlation ranged from 0.976 to 0.989. When CDP was applied to three groups of patients grouped on the basis of scores obtained in WHO BREF-QOL, statistically significant difference was obtained between the groups in ANOVA F test [F (df2, 57) =30.98; p=<0.01], proving that CDP has construct validity.

Conclusion: CDP will help healthcare workers to quantify in depth data about different attributes of distress faced by diabetic foot ulcer patients, and might help in early psychological interventions for vulnerable patients.

Keywords: Diabetic foot ulcer, Composite distress profile, Biobehavioural Distress.

Please cite this article as: Varkey SM, Lucita M, Punnoose VP. Composite Distress Profile: Development of a standardised measure for quantification of multidimensional distress faced by patients with diabetic foot ulcer. Kerala Journal of Psychiatry 2016; 29(1). Available at http://kjponline.com/index.php/kjp/article/view/86/pdf

INTRODUCTION

Biobehavioural distress is comorbid in most chronic health conditions, especially if they have caused limitations in most spheres of daily life.[1] Chronic diabetic foot is a condition which produces significant distress in different domains. History of health care reveal increased attention to biological symptoms of patients.[2] Individual's response to chronic diseases affect all dimensions of health in varying proportions, but its measurement is most often limited to biologic domain and less often to behavioural domain. Treatment will be unsuccessful if we focus only on physical ailment, neglecting rest of human totality.[3] WHO recognized this void earlier and explores spiritual, social, psychological domains of health in addition to physical domain.[4] Words and actions when unlooked will remain hidden beyond scene. In chronic illnesses, patients often face uncertainties. Most often, this is not looked for by healthcare professionals and remains hidden. Illness demands ongoing adjustment in multiple life domains. In such situations, health workers should have an a priori deductive approach about biobehavioural distress.[5]

Diabetic foot ulceration is an ever-increasing problem and no evidence is available regarding reduction in its prevalence or in the rates of amputation over previous decades.[6] There is a need for holistic wound care in diabetic foot patients, because it is a multifaceted issue that requires a multifaceted response.[7] According to International Diabetes Federation, around the world there were 415 million people living with diabetes in 2015. It is also predicted that by 2030 the countries with the largest number of diabetic patients will be India, China and USA. By 2040, one in 10 adults will have diabetes, resulting in 642 million people with diabetes worldwide.[8]

WHO has predicted that, going by the current trend, India will become the "diabetes capital of the world" by 2025.[1] Kerala is the diabetes capital of India, with a prevalence of diabetes as high as 20% — double the national average of 8%.[1] The prevalence of diabetes in Thiruvananthapuram was 17% compared to 15% in Hyderabad and New Delhi, 4% in Nagpur and 3% in Dibrugarh.[7]

The real burden of diabetes is due to its associated complications which lead to increased morbidity and mortality.[9] Diabetes appears to dramatically increase the risk of lower extremity amputation because of infected, non-healing foot ulcers.[10] Estimates of the lifetime probability of diabetics developing a chronic foot ulcer are between 10–25%. 73,000 non-traumatic lower limb amputations were performed in adults aged 20 years or older with diagnosed diabetes in America.[11] It is estimated that in Australia, diabetes amputation rates are increasing, up to 14 per 100,000 population.[12]

A study by Abraham, Jyothylekshmy and Menon, in 277 diabetic patients, showed that 41.51% had chronic diabetic foot ulcers.[13] A retrospective study done in 2013 at Amrita Institute of Medical Sciences in Kerala, in 325 diabetic foot ulcer patients, by Amit Kumar, C Jain, Ajit Kumar Varma and Mangalanandan, showed that 10.5% of patients underwent major amputations due to diabetic foot ulcers.[10] A cross sectional survey on 118 foot ulcer patients of south Kerala demonstrated considerable economic burden imposed on households, leading to debt (18%), selling of assets (8%) and loan (7%).[11]

Biobehavioural distress is comorbid in most chronic health conditions, especially if they have caused limitations in locomotion.[12] Assessment of biobehavioural distress in multiple domains will provide greater understanding about the construct — not only about the physical complaints, but also about other major domains of behavior. A tool to quantify composite distress will definitely contribute to the field of liaison and primary care psychiatry. Locally

developed instruments that can be used in primary care, however, are very few and definitely this stream of research will aid in holistic health care delivery.

Patients with chronic conditions like diabetic foot ulcer are on tenterhooks about their prognosis. This puts them in a state of distress which prevents them from experiencing delight in anything they cherished in their life before the diagnosis. There is an increased risk of negative outcomes for distress prone individuals. An engrossing distress may be the end result of functional limitation in various facets of life, which necessitates its thorough delineation in various dimensions of health.[13] Most of the time, it is not detected earlier and only gets noticed if it gets transformed into depression, anxiety or when it severely affects the day to day functioning of the client. Prompt quantification of distress may act as an interlude before intervening towards positive adjustment.[14] Even when clinicians eschew the diagnosis of anxiety and depression, patient may be experiencing milder forms of psychological distress which might signal poor adjustment and the need for clinical intervention.

Composite measurement of physical, intrapersonal, interpersonal, social and spiritual dimensions has not been addressed in the literature. A number of scaling measures have been published in the literature with no relative consensus.[15] Tool for comprehensive screening in multiple dimensions is not available but is available for separate constructs. Distress thermometer, a tool developed by Hillingdon Oncology & Palliative Care Team of West London cancer network, measures similar concept like physical problems, emotional problems, family problems, practical problems and spiritual/religious concerns, but its scoring is ambiguous and moreover it is not validated in diabetic foot ulcer patients. Scales for measuring individual constructs are available, such as Marlowe-Crowne Social Desirability Scale, Perceived Stress Scale-10 Item, WHO-5 and PHQ-9 Scales, Beck Depression Inventory –II, State Trait Anxiety Inventory, 20-item trait anxiety (STAI-T) subscale, etc. But measures like these quantify different constructs, necessitating their use in individual sessions, which would be cumbersome for the patient.

Composite Distress Profile (CDP), the tool we developed in this study, does this in a comprehensive manner, and its measurements can be used for referral services. We intended to develop a new scale for measuring composite distress that can describe the distress level in different domains, and would reflect overall distress, taking into account various indicators. CDP scoring indicates the degree to which patient experiences stress that continues without relief in different dimensions of health. It was envisaged that the new scale would be useful across cultures and setups, and can be used in different clinical scenarios involving various methods.

OBJECTIVES

- To develop a cross culturally appropriate tool for diagnosis of distress in different domains of life among diabetic foot patients.
- To standardise Composite Distress Profile by establishing its psychometric properties.

MATERIALS AND METHODS

In the first part of tool development procedure, a focus group discussion with 11 patients having Wagner 1 or 2 diabetic foot ulcer were conducted at Pampady taluk hospital.

After establishing content validity of the items (as described in Results section), we proceeded to second part of the tool development procedure, where nonexperimental cross sectional design was used. Sixty consecutive patients brought with diabetic foot ulcer from

January 2015 to January 2016 were selected for the study from six general and taluk hospitals of Kottayam district irrespective of their sociopersonal variables. Informed consent from the patient was taken after excluding those with psychiatric illness. CDP Questionnaire, Subjective wellbeing inventory by Sell and Nagpal, and BREF- QOL by WHO were administered by the first author. CDP was applied for a second time after an interval of two weeks.

The permission for the study was granted from Directorate of Health Services.

Statistical analysis

Statistical analysis of the data was performed using SPSS software pack version 17 (Chicago SPSS Inc.). Statistical measures used include Karl Pearson correlation and ANOVA where the level of significance was kept at standard 0.05 levels.

RESULTS

Assessment of content validity

Item development was done using focus group discussion conducted at initial part of the study. Verbatim of 11 patients who attended that discussion was coded and theme for the individual items were organized under five domains. Consensus of nine nurses, nine nurse educators, three surgeons, three psychologists, three psychiatrists and three chaplains were sought. From the various items initially considered for the scale, the final version was agreed through consensus method following discussion among the faculties. As a first step in evaluating validity, we chose clear and valid items from the constructed ones. An expert multidisciplinary panel of nine judges selected from the group of experts listed earlier were formed for the scientific advice regarding necessity of individual items. They rated each item as essential or not, and also rank ordered the items for selection.

Subsequently, item wording and sequencing was done using simple and short language to enable easy reading. Agreement was determined between the experts using content validity index. Content validity ratio was also computed using Lawshe's formula. Those items which gained CVI >.80 were included in the final tool. Greater levels of content validity existed, as larger numbers of panellists agreed that a particular item is essential.

Five domains and number of items in them

1. Physical distress -10
2. Intrapersonal distress-10
3. Interpersonal distress -10
4. Social distress-10
5. Spiritual distress-10

Total Items-50

Scoring key

- Never / not applicable: 0
- Rarely: 1
- Sometimes: 2
- Most often: 3
- Always: 4

The scores can be added to find out total distress, with possible total scores between 0 and 200.

Interpretation of total CDP according to quartile range

- <65=Mild distress
- 66-135=Moderate distress
- >136=Severe distress

Table 1: Mean CDP scores of the three groups which had subaverage, average and good quality of life on BREF-QOL

BREF VALUE	n	CDP SCORE MEAN±SD	F (df=2,57)	p
<50	21	161.10±35.86	30.98	<0.01
50-80	24	122.96±37.47		
>80	15	71.79±33.73		

CDP=Composite Distress Profile

Interpretation of domain wise CDP according to quartile range

- <13=Mild distress
- 14-26=Moderate distress
- >27 =Severe distress

Assessment of construct validity

Measures of affect necessitate establishment of construct validity. Construct validity is the degree to which a tool confirms to the predicted correlations with other theoretical propositions. Construct validity is usually determined by using: 1) Contrasted group approach 2) Hypothesis testing approach 3) Multitrait–multimethod approach or 4) Factor analysis.

Construct validity of CDP was computed by doing contrasted groups approach using BREF-QOL. We classified the 60 diabetic foot ulcer patients into having subaverage, average and good quality of life with BREF-QOL. We then administered CDP to the three groups. Mean CDP of the three groups were then compared using ANOVA F test (Table 1). The significant difference obtained between these groups' mean scores is evidence for construct validity of CDP.

Assessment of criterion validity

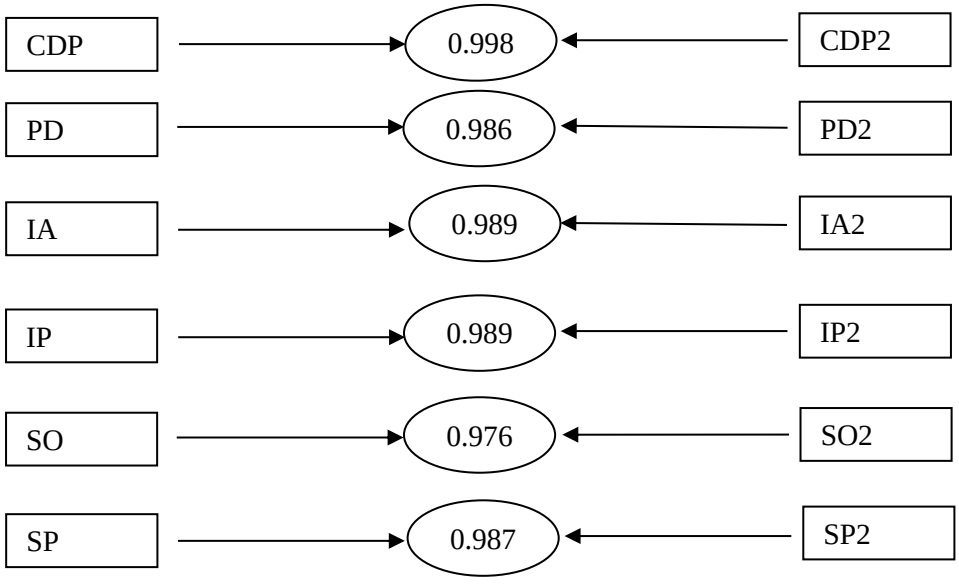
Criterion or concrete validity is the extent to which a measure is related to an outcome. A known standard must be tested against itself to measure the criterion validity of a test. Establishing criterion related validity also involves determining the relationship between an instrument and an external criterion.[15] Comparing the test with an established measure is known as concurrent validity; testing it over a period of time is known as predictive validity. It is not necessary two use both the methods.

Criterion validity was established for CDP by comparing CDP scores with scores obtained in Subjective Well-Being Inventory(SUBI), a positive measure of wellbeing. Pearson correlation was used for the comparison. CDP scores showed significant negative correlation with SUBI scores ($r=-0.725$ at $p<0.01$ level).

Assessment of reliability

Coefficient of stability for CDP was assessed by test-retest reliability of measurements gathered from 60 diabetic foot ulcer patients using CDP on two different occasions two weeks apart. Pearson's product moment correlation was computed. The results are provided in figure 1.

Fig 1: Overall and domain-wise intrarater reliability of Composite Distress Profile



CDP 1&2: Composite Distress Profile first and second measurements; PD1&2: Physical distress first and second measurements; IA 1&2: Intrapersonal distress-first and second measurements; IP1&2: Interpersonal distress first and second measurements; SO1&2: Social distress first and second measurements; SP1&2: Spiritual distress first and second measurements

Translation and back translation

As we intended to develop a tool for use among diabetic foot ulcer patients anywhere in the world, English version was constructed first, followed by Malayalam version which was constructed using forward and expert back translation according to WHO translation guidelines.[22] In the process of translation, first the forward translation of CDP in English to Malayalam was done by a Malayalam expert whose mother tongue is Malayalam and who knows English language and culture. It was followed by a bilingual expert panel back-translation. Then an independent translator translated it back to English. Discrepancies were discussed and further work (forward translations, discussion by the bilingual expert panel, etc.) was repeated till a satisfactory version was reached. Pre-testing and cognitive interviewing were done before approving the final version.

Strengths of the study

- This type of tool will help in liaison psychiatry.
- CDP is standardised.
- CDP is highly suitable for use in cross cultural settings.
- CDP would be useful for assessment or prediction of negative coping strategies.

Limitations

- Sample size was limited.
- Sensitivity, specificity and predictive value for subclinical depression were not established due time limitations.
- Factor analysis was not employed.

DISCUSSION

Items in the five CDP domains

Chronic illnesses such as presence of non-healing wounds affect all spheres of an individual. Psychological distress often goes unrecognized in persons with chronic illness, with potentially detrimental consequences for patients and their families. Distress is a state of suffering, affliction, painful trouble or struggle that affects the mind or body. We envisaged distress as an oppressive condition of physical, intrapersonal, interpersonal, social or spiritual hardship existing or occurring within the individual self or mind.

Physical distress is one of the consequences of poor physical health.[14] Its disease specific quantification provides an image of seriousness of health issues. Exhaustive and prolonged wound healing trajectory necessitates partial dependence on others, which causes physical distress which usually surfaces with the first clinical interview. In this questionnaire, we included some diabetic foot ulcer related physical difficulties such as walking difficulty, fear of fall related to offloading of foot, inadequacy in performance of hygienic needs, hindrance in performance of activities of daily living, pain in the affected leg, pain in the unaffected leg due to offloading, sleeplessness, difficulty in performing elimination needs, sexual problems and peri ulcer itching.

Lengthy wound care and debridement regimens lead to intrapersonal distress.[15] One's inmost feelings will be bewildered. By discussing intrapersonal distress, a person can describe his or her uncomfortable feelings and distressing thoughts. In intrapersonal distress, we included some diabetic foot ulcer related problems such as inability to get through demands of daily life, guilt about diabetes mismanagement in past, anxiety about wound healing, worries and frustrations, lack of self-esteem, body image disturbance, fear of bad odour emanating from the wound, inadequacy in self appraisal, distress when thinking of financial obligation caused to others by this condition, role strain or insecurity.

Understanding and resolving interpersonal problems is considered an important step in measuring distress of diabetic foot patients.[16] Patients consider themselves as a burden when their care needs increase and concern of caregiver increments. In interpersonal distress, we included some diabetic foot ulcer related problems such as feeling that family members are emotionally not supportive, feeling that significant others are emotionally not supportive, inability to receive help in decision making, any thwart in previously warm relationship, inability to receive errand or immediate help, dislike from others, deterioration in relationship with life partner, and unexplained anger.

Locomotor problems lead to deficiency in social and diversional activities in diabetic foot ulcer patients.[17] Missing of opportunities causes a feeling of chronic sorrow. In social distress, we included problems such as inability to continue occupation, difficulty due to loss of income, inability to meet treatment expenses, difficulty in attending social gatherings, possibility of being branded incompetent, fear of being thrown out from normal life, inability to perform responsibilities, loss of peace due to social isolation, and boredom due to inability to perform routine activities.

Spiritual distress often impacts health negatively.[18] Diabetic foot patients feel distressed when they compare themselves with their counterparts who did not develop chronic ulceration. In spiritual distress, we included some problems like thought that God does not exist, questioning belief systems, spiritual emptiness, thinking that why this happened to me alone, God has disrupted His relationship,

punishment due to some ancestral sins, guilt in the kind of life led in the past, fed up with the life, withdrawal from religious activities, and doubts about the meaning of burdens in life.

Relevance of the new tool

As age increases, higher the morbidity and distress. A study from north India on morbidity profile and its determinants stressed the need for distress assessment.[12] Moreover, providers and patients frequently underestimate the seriousness of psychological distress[19] comorbid with chronic illness, assuming that it is a natural reaction rather than a potentially serious condition.[20] Functioning and disability refers to three key components — body structure and functional impairment, activity limitation, restriction in participation and self-abnegation.[20] Lack of adequate studies about biobehavioural distress exhibited by persons suffering from chronic conditions prevents the formulation of conceptual models of distress.[21] Paucity of studies about biobehavioural distress and its role in different psychopathologies will pose a hindrance in creation of efficacious prevention and treatment approaches. Operational definitions for its measurement have been loose and varied. Outcome of a diagnosis depends upon various factors that can influence distress tolerance. Distress exhibited by the patients depends on the physical consequences they encounter, the disability they suffer, and their particular circumstances and surroundings. Assessment should ideally consider all these factors. Differentiating between normal and transient levels of psychological distress and affective states of depression and anxiety is critical to effective treatment. CDP will substantially contribute in quantitative and qualitative assessment of biobehavioural distress, and is an exemplary screening instrument which acts as a stitch in time in primary prevention of psychological decline. It aids indigent people to express their distress. It may also help in identification of resilient individuals who may score low on distress. Use of CDP will make interview data of patients deep and rich. CDP will be also of help in conducting population surveys and in monitoring trials and treatment effects.

CONCLUSION

We intended to develop a simple tool which will help in identifying or revealing those who are in distress Completion of entire test requires that the client be reasonably cooperative, motivated, and has at least moderate span of attention. The task of administering and scoring CDP is very simple. It has only 50 items and can be administered in less than 10 minutes.

Scoring and interpretation can be done easily. Summing of coded item scores within each domain of CDP is done followed by summing of all five domain scores to obtain total CDP scores. It allows computing overall and five domain-specific functioning scores.

Validity and reliability tests performed shows that CDP has got good psychometric qualities — hence it can be used in diabetic foot ulcer patients as a reliable tool for measuring distress across five domains. A trained health professional can use this tool for screening and differentiate between normal and morbid levels of psychological distress, especially in regions where accessibility of psychologists and psychiatrists is limited. A paper-and-pencil version of CDP can be self-administered.

REFERENCES

1. Dey AB, Soneja S, Nagarkar KM, Jhingan HP. Evaluation of the health and functional status of older Indians as a prelude to the development of a health programme. Natl Med J India;14(3):135–8.
2. Saylor C. The circle of health: a health definition model. J Holist Nurs 2004;22(2):97–115.
3. Spiegel D. Healing words: emotional expression and disease outcome. JAMA 1999;281(14):1328-9

4. Olive P. The holistic nursing care of patients with minor injuries attending the A&E department. Accid Emerg Nurs 2003;11(1):27-32.
5. Powell T. Consultation-liaison psychiatry and clinical ethics: representative cases. Psychosomatics 1997;38(4):321-6.
6. Frykberg RG, Zgonis T, Armstrong DG, Driver VR, Giurini JM, Kravitz SR, et al. diabetic foot disorders: a clinical practice guideline. J Foot Ankle 2006; 45(5 Suppl):S1-66.
7. Mohan V, Sandeep S, Deepa R, Shah B, Varghese C. Epidemiology of type 2 diabetes: Indian scenario. Indian J Med Res 2007;125(3):217–30.
8. American Diabetes Association [Internet]. Statistics About Diabetes. [cited 2nd October 2016] Available from: www.cdc.gov/diabetes/data/statistics/2016statisticsreport.html.
9. Lazzarini PA, O'Rourke SR, Russell AW, Clark D, Kuys SS. What are the key conditions associated with lower limb amputations in a major Australian teaching hospital? J Foot Ankle Res 2012;30;5(1):12.
10. Kumar A, Jain C, Varma AK, Mangalanandan, Kumar H. A decade of experience in managing diabetic foot at amrita, India's largest diabetic limb salvage centre. J diabet foot complicat 2013;5(1):15–7.
11. Sithara SP. The impact of diabetic foot ulcer on health related quality of life (HRQL) and employment among rural diabetic population in south Kerala. SCTIMST study reports. Dissertation for Master of Public Health 2012; [cited 2nd October 2016] Available from: http://dspace.sctimst.ac.in/jspui/bitstream/123456789/2133/1/MPH_6150.pdf
12. Pande N, Tewari S. Understanding Coping with Distress due to Physical Disability. Psychol Dev Soc 2011; 15(2): 95-110.
13. Jyothylekshmy V, Menon AS, Abraham S. Epidemiology of diabetic foot complications in a podiatry clinic of a tertiary hospital in South India. Indian Journal of Health Sciences 2015, 8(1):48-51.
14. Bijl R, Graaf R de, Hiripi E, Kessler R. The prevalence of treated and untreated mental disorders in five countries. Health Aff 2003;22(3):122-33.
15. Joshi K, Kumar R, Avasthi A. Morbidity profile and its relationship with disability and psychological distress among elderly people in Northern India. Int J Epidemiol 2003;32(6):978–87.
16. Passik S, Dugan W. Oncologists' recognition of depression in their patients with cancer. J Clin Oncol 1998; 16(4):1594-600.
17. ICF, WHO. Towards a common language for functioning, disability and health. 2009.
18. Edelman C, Mandle C, Coralli C. Health Promotion Throughout the Lifespan. Nurse Pract 1987;23(1):25-36.
19. Kendler KS, Gardner CO. Dependent stressful life events and prior depressive episodes in the prediction of major depression: the problem of causal inference in psychiatric epidemiology. Arch Gen Psychiatry 2010; 33(1):82.
20. Pargament KI, Koenig HG, Tarakeshwar N, Hahn J. Religious coping methods as predictors of psychological, physical and spiritual outcomes among medically ill elderly patients: a two-year longitudinal study. J Health Psychol2004;9(6):713-30.
21. Lewis-Beck M, Bryman A, Futing Liao T. The SAGE Encyclopedia of Social Science Research Methods [Internet]. California: Sage Publications; 2004 [cited 2nd October 2016] Available from: http://methods.sagepub.com/reference/the-sage-encyclopedia-of-social-science-research-methods.
22. World Health Organization [Internet]. Process of translation and adaptation of instruments. [cited 2nd October 2016] Available from: http://www.who.int/substance_abuse/research_tools/translation/en/

Source of support: None
Conflict of interest: None declared
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First submitted: 5th October 2016
Published online: 8th December 2016