

Initial Construct Cross-Cultural Validation of the Short Form 36 for Quality of Life Assessment of Systemic Lupus Erythematosus Patients in Singapore

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Abstract

The objective of this study was to determine if the Short Form 36 (SF-36) Health Survey Questionnaire measures differences in quality of life between lupus patients and healthy controls in Singapore. A cross-sectional pilot study was conducted on consecutive English-speaking, female Chinese lupus patients seen at a Rheumatology unit. Healthy volunteers were recruited as controls during the same time period. All subjects completed the United Kingdom version of the SF-36. Lupus disease activity was assessed using the British Isles Lupus Assessment Group (BILAG) index and converted to a global score. Lupus-related damage was measured using the Systemic Lupus International Collaborating Clinics/American College of Rheumatology Damage Index (SLICC/ACRDI). The main outcomes measured were the mean SF-36 scale scores for lupus patients and healthy controls.

Thirty-six lupus patients and 76 controls were included in the study. All subjects were English-speaking, Chinese female between 21 and 53 years of age. The mean age of patients and controls was 31.9 and 29.0 years respectively. Lupus patients had lower mean scale scores than controls for physical functioning (73.0 versus 89.7, $P < 0.0027$), bodily pain (71.0 versus 81.4, $P < 0.027$), physical role functioning (55.7 versus 89.5, $P < 0.0001$) and general health (47.4 versus 51.8, $P < 0.05$). Mean scale scores for vitality, social and emotional role function and mental health were similar in both groups. Ten patients had active disease (BILAG global scores of 3 to 14) and 13 patients had lupus-related damage (Damage Index scores of 1 to 7). These preliminary data suggest that the SF-36 Health Survey may be able to measure differences in quality of life between lupus patients and healthy controls in Singapore.

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Introduction

Quality of life is increasingly being recognised as an important health outcome measurement for patients with chronic illness.¹ Quality of life scales measure changes in physical, functional, psychological and social domains of health and reflect the patient's perception of his or her state of health.² These scales measure the impact of illness and therapy related morbidity, allowing relatively objective measurements of quality of life and more precise assessments of outcome than mortality data. Several non-disease specific scales have been devised and validated in Caucasian populations,³ but cultural differences between the East and the West may affect their validity in other populations.³ These scales

therefore need to be validated to confirm their psychometric properties and usefulness in the socio-cultural environment in Singapore. Normal values for the Singapore population also need to be defined as these are known to vary among cultures. To our knowledge, there are no validated non-disease specific measures of quality of life in Singapore. We therefore conducted a pilot study in a cohort of English-speaking Chinese lupus patients as part of a project to assess the validity of the Short Form 36 (SF-36) Health Survey Questionnaire in Singapore.

Developed in the United States from the well-known Rand Corporation's Medical Outcomes Study (MOS), the SF-36 Health Survey Questionnaire is an interna-

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tionally utilised, self-administered questionnaire,* measuring quality of life in eight areas of perceived health using a single multi-item scale. Cross-validation and normative data have been established in the United Kingdom, France and other Western populations.⁵⁻⁷ The SF-36 is a generic scale specifically designed for ambulatory patients, and can therefore also be used to compare quality of life in patients with different diseases.⁸ Conceptually, it may also be used to monitor changes in quality of life resulting from changes in the underlying disease process, co-morbid diseases or treatment.

Materials and Methods

A cross-sectional study was conducted on consecutive English-speaking, female Chinese lupus outpatients or inpatients between the ages of 20 and 60 years followed up at the Department of Rheumatology and Immunology, Tan Tock Seng Hospital. All patients fulfilled the 1982 American Rheumatism Association revised criteria for systemic lupus erythematosus. To avoid possible confounding factors due to gender, ethnicity and co-morbid conditions not assessed in the Damage Index (see later), males and patients of non-Chinese ethnicity or with active infectious diseases were excluded from this pilot study. Permission to use the SF-36 was obtained from the Medical Outcomes Trust.* All patients completed a questionnaire containing the United Kingdom version of the SF-36. A rheumatologist assessed each patient for disease activity using the British Isles Lupus Assessment Group (BILAG) index⁹ and for lupus-related damage using the Systemic Lupus International Collaborative Clinics/American College of Rheumatology Damage Index (SLICC/ACRDI).¹⁰ BILAG scores for each system were converted to a global score using the method of Gladman et al.¹¹ Active disease was defined as a BILAG global score of more than 2. Controls (n = 76) were English-speaking, female Chinese between the ages of 20 and 60 years who completed a similar questionnaire. A screening question inquiring about the presence of any illness was included in the control questionnaire. Individuals who reported medical problems of any kind were excluded from the control group. SF-36 raw scores were computed for lupus patients and controls and transformed into scale scores using recommended methodology.⁸ Differences in mean scale scores were assessed using the unpaired, 2-tailed Student's t-test, considered statistically significant at $P \leq 0.05$.

Results

The study cohort consisted of 36 English-speaking female Chinese lupus patients and 76 English-speaking female Chinese volunteers with no illnesses by self report. Demographic data of the study cohort are summarised in Table I. Ten lupus patients (27.8%) had

active disease (BILAG global score >2) and 13 lupus patients (36.1%) had disease related damage (Damage Index ≥ 1). The median BILAG global score was 2, and was most commonly due to lymphopaenia in otherwise inactive lupus patients.

The mean SF-36 scale scores for 8 domains of perceived health in lupus patients and controls are summarised in Table II. Lupus patients had lower mean scale scores than controls in the areas of physical functioning, role-physical, bodily pain and general health. Mean scale scores for vitality, social functioning, role-emotional and mental health were similar in both groups.

TABLE I: DEMOGRAPHIC AND DISEASE PROFILES OF THE STUDY COHORT

	Lupus patients	Controls
Number	36	76
Mean age in years (range)	31.9 (21 to 53)	29.0 (21 to 53)
Median BILAG Score (range)	2 (0 to 14)	NA
Median Damage Index Score (range)	0 (0 to 7)	NA

BILAG: British Isles Lupus Assessment Group; NA: not applicable

TABLE II: MEAN SF-36 SCORES FOR LUPUS PATIENTS AND CONTROLS

Domain	Lupus patients	Controls	P value
Physical Functioning	73.0 (10 to 100)	89.7 (15 to 100)	0.0027
Role-Physical	55.7 (0 to 100)	89.5 (0 to 100)	0.0001
Bodily Pain	71.0 (22 to 100)	81.4 (22 to 100)	0.027
General Health	47.4 (15 to 62)	51.8 (30 to 72)	0.05
Vitality	43.8 (20 to 60)	44.8 (20 to 60)	0.61
Social Functioning	45.9 (12.5 to 75)	45.8 (12.5 to 75)	0.95
Role-Emotional	71.4 (0 to 100)	74.7 (0 to 100)	0.67
Mental Health	55.1 (28 to 72)	56.3 (24 to 72)	0.54

Discussion

Item measurement theory proposes that there is an actual quality of life that cannot be measured directly but only through a series of questions, each of which measures the same concept. The scores from these questions, if correctly devised, will differ from the actual quality of life score only by random error of measurement.² The objective of validating the SF-36 is to determine how accurately it measures this actual quality of life, and is a multi-stage process of assessing construct and criterion validity, reliability and sensitivity to change and determining population-based normal values.¹²

Construct validity assesses the degree to which a scale measures patients' perceptions of health, and is suggested by the ability of the instrument to discriminate between the health scores of healthy individuals and patients with varying severity of diseases. Construct validity of the SF-36 is suggested by the results of this pilot study, where lupus patients had lower mean scale

scores than healthy controls in 4 out of 8 domains of perceived health. Criterion validity is the correlation of the scales to be validated with some measure of the disorder under study, ideally a "gold standard" which has been used and accepted in the study of the disorder. Sensitivity to change assesses the ability of the scales to detect changes in health status that may occur, for example with worsening or improvement of disease. Reliability is assessed in the areas of internal consistency and stability. Internal consistency is the degree of homogeneity of the items in a scale as measured by Cronbach's alpha coefficient.¹³ Stability is a measure of how comparable the results of the scale are when they are used in a variety of situations, and are measured by test-retest correlation where the scale is administered to the same subject twice within a short period of time. Lupus is a chronic illness affecting multiple organ systems, with a disease course characterised by flares and remissions and is well known to affect both physical and mental functioning.¹⁴ It therefore provides a suitable testbed for assessing the various domains of the SF-36 cross-sectionally (construct and criterion validity) and prospectively (sensitivity to change) using validated, internationally accepted measures of disease activity and damage.¹⁵ A prospective study of quality of life of lupus patients in Singapore is in progress to assess the validity of the SF-36 in these areas.

The lack of significant differences between lupus patients and controls in the mean scale scores for vitality, social functioning, role-emotional and mental health may reflect either a lack of construct validity of the SF-36 in these domains in the Singapore socio-cultural context or a true lack of difference in these domains, possibly due to the small sample size in this pilot study. A true lack of difference between lupus patients and controls is suggested by the fact that no difference in scale scores was demonstrated for domains assessing social and mental health, whereas significant differences were demonstrated for domains assessing physical health. This pattern is unlikely to be due to chance and suggests that the lupus patients studied-the majority of whom had inactive disease and little or no disease-related damage-were able to cope with the mental and social impact of their disease but were hindered in physical functioning. A larger prospective study, controlling for the effects of demographic, socio-economic and disease-related variables on SF-36 scores, is in progress to confirm the finding of a lower quality of life in lupus patients in Singapore and to determine the factors influencing this.

The availability of an objective, reproducible measure

of quality of life in Singapore would facilitate the objective assessment of quality of life in various chronic illnesses, allow identification of factors affecting the quality of life and enable assessment of interventions to improve the quality of life of these patients. The data from this pilot study suggest that the SF-36 Health Survey Questionnaire may be able to measure differences in quality of life between lupus patients and healthy controls in Singapore. A prospective study is in progress to further validate the SF-36 for use in assessing the quality of life of lupus patients in Singapore.

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