Quality of Well Being in Patients with Fibromyalgia

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ABSTRACT. ***Objective.*** The Quality of Well-being Scale (QWB) is a generic measure of health related quality of life that can be used for population monitoring, measurement of clinical outcomes, or cost effectiveness analysis. We report data on the validity of the QWB for patients with fibromyalgia (FM) and compare the effect of FM to that of other chronic diseases.

Methods. The participants were 594 people recruited from a private health maintenance organization with a confirmed diagnosis of FM. The QWB was administered, along with measures of self-rated health status, physical functioning, pain, stiffness, anxiety, sleep, and depression. The QWB places levels of wellness on a continuum ranging from 0.0 (for death or the equivalent of being dead) to 1.0 (for optimum functioning without symptoms).

Results. Patients with FM had mean QWB scores of 0.559 (SD 0.074), which is lower than scores reported for patients in most other chronic disease categories. QWB was significantly correlated with measures of physical functioning, stiffness, anxiety, depression, pain, and sleep quality.

Conclusion. Evidence supports the validity of the QWB for patients with FM. Patients with FM obtain lower scores on the QWB than patients with diagnoses of chronic obstructive pulmonary disease, rheumatoid arthritis, atrial fibrillation, advanced cancer, and several other chronic diseases. Although FM is generally considered a syndrome rather than a disease, substantial disability is experienced by people with this diagnosis. (J Rheumatol 2000;27:785-9)

Key Indexing Terms:
FIBROMYALGIA
QUALITY OF WELL BEING SCALE
QUALITY OF LIFE
OUTCOMES MEASUREMENT

Quality of life has become an important outcome in studies of rheumatic disease. Most studies in rheumatology use disease-specific measures of quality of life such as the Arthritis Impact Measurement Scale (AIMS)[1] or the Health Assessment Questionnaire (HAQ)[2]. These measures have the advantage of asking questions specific to musculoskeletal problems. However, some studies have failed to show that they are more sensitive to medical interventions for arthritis than are more general generic measures[3]. The generic measures may be less sensitive, but are required for some policy analyses.

Policy analysis requires that a broad range of policy options be considered. The options must be compared because very different programs compete for the same funds. The options are usually diverse, ranging from prevention to acute care, to chronic care, rehabilitation, and longterm care. For these very different options to be compared directly, they must be evaluated using a common set of rules and measures. Investigators in both the public and private sectors have struggled to find appropriate methodologies to evaluate health care technologies. In 1993, the US Department of Health and Human Services appointed a multidisciplinary group of methodologists to recommend standardized strategies for the evaluation of health care. The panel concluded that standardized outcomes analyses be conducted to evaluate the cost effectiveness of medical care[4]. These analyses require preference weighted measures of health related quality of life. Although there has been considerable interest in measuring the cost effectiveness of treatments for fibromyalgia (FM), little is known about the validity of general outcomes measures for these patients.

We use a method known as the Quality of Well-being Scale (QWB), which is one of the general methods that can be used to estimate quality adjusted life years (QALY) for policy analysis. There has been a trend toward the use of measures that are unique to a given illness. These disease-specific measures have limited usefulness when making comparisons between different disease states. The QWB is a general measure that may conceivably be used in any disease population. Generic measures can be used to compare the value of treatments for different conditions. However, it is important to determine the validity of generic measures, such as the QWB, for particular diseases.

The QWB can be used to produce a single number that represents the current impact of FM. In policy analysis QWB scores are combined with survival data to produce a comprehensive expression of health outcome. When integrated over time, this number represents the combined effects of morbidity and mortality upon patients with FM. Ultimately, this will allow an expression of the effect of FM upon the number of QALY lost to this disease. Reports have offered general valid-

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Supported by NIH grants AR44020 and P60 AR40770 and AHCPR grant 5R01 HS09170.

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Submitted February 23, 1999 revision accepted July 23, 1999.

ity evidence for the QWB system, as well as evidence for its validity in specific disease categories[5–9]. However, application of this model to FM requires specific validation for this patient group.

MATERIALS AND METHODS

Participants. The participants were 594 private health maintenance organization (HMO) members who agreed to participate in a year long intervention testing the effects of social support and education on health and well being. To be eligible, HMO members needed a confirmed physician's diagnosis of FM. The diagnosis was confirmed on entry to the study through a tender point examination performed by trained project staff using the American College of Rheumatology criteria for FM[10]. These criteria included a history of widespread pain, which included pain on both sides of the body, above and below the waist, and axial skeletal pain present for at least 3 months; and pain in 11 of the 18 tender point sites when palpation was performed with a force of 4 kg. Informed, written consent was obtained from all volunteers before they were admitted to the study.

The average age was 53.84 (SD 11.35) years. The mean duration of symptoms was 13.733 (SD 13.113) years. Years of symptoms ranged from < 1 year to 66 years. Demographic characteristics of the sample are summarized in Table 1.

Quality of Well-being Scale. The QWB is a comprehensive measure of health related quality of life that includes several components. First, it obtains observable levels of functioning for the previous 6 days from 3 separate scales: Mobility, Physical Activity, and Social Activity. These scales each contain a variety of items. Second, each patient identifies her or his most undesirable symptom or problem from a list of 27 items. Then the observed level of function and the subjective symptomatic complaint are weighted by preference, or the utility for the state, on a scale ranging from 0 (for dead) to 1.0 (for optimum function). The weights have been obtained from independent samples of 856 judges who rated the desirability of observable health states. Several studies have shown that the weights do not vary as a function of demographic variables, including race, income, and sex[11]. Further, most evidence indicates that the weights do not vary systematically as a function of prior experience with the rated health state[11]. Using this system, it is possible to place the general health status of any individual on the continuum between death and optimal functioning for any specified time.

The QWB has been used in a wide variety of clinical and population studies[12,13]. In addition, the QWB scale has been used in clinical trials and studies to evaluate therapeutic interventions in a wide range of medical and surgical conditions. These include chronic obstructive pulmonary disease[6], acquired immunodeficiency syndrome[14], cystic fibrosis[7], diabetes mellitus[15], atrial fibrillation[16], lung transplantation[17], arthritis[18,19], cancer[20], sinus disease[21], schizophrenia[22], and a variety of other conditions[20]. For example, in patients with arthritis, the correlation between the QWB and the physical component of the AIMS has been estimated as –0.58. The relationship is negative because higher QWB scores are associated with lower AIMS scores[19]. The version of the QWB used for this study requires a trained interviewer. However, a self-administered version is now available. Both versions can be completed in less than 15 minutes.

The validity of QWB items for older adults was reported in a study of 71 older adults who completed the QWB questionnaire and then were observed performing a variety of tasks, including tying shoes, buttoning, hooking, using safety pins, zippers, and Velcro, walking and arising. There were significant linear associations between QWB scores and time to walk 30 feet ($p < 0.01$), manual dexterity ($p < 0.002$), grip strength ($p < 0.01$), need for assistance in standing ($p < 0.01$), and several other observed behaviors. Andresen and colleagues administered the QWB and several other measures to 200 older adults in the Group Health Cooperative in Seattle. They found that the QWB was significantly related to independent assessments of chronic disease[23]. A variety of studies show that the QWB has a reliability exceeding 0.90 for most populations[13] and can be completed in times comparable to other popular measures such as the SF-36[24].

Table 1. Participant demographics.

Variable	%
Sex	
Female	95.3
Male	4.7
Highest level of education	
Grade school	0.3
High school	18.4
Some college	50.2
Bachelor degree	15.7
Master degree	10.4
Doctorate	0.8
Other professional certification	4.0
Decline to state	0.2
Marital status	
Single	10.8
Married/remarried	64.0
Widow/widower	4.4
Divorced/separated	20.7
Decline to state	0.2
Employment status	
Part-time	15.5
Full-time	33.8
Unemployed	7.6
Retired	22.7
Disabled	11.6
Homemaker	8.4
Decline to state	0.3
Household income	
< $10,000	5.1
$10,000 to $30,000	25.9
$30,000 to $50,000	36.4
$50,000 to $70,000	16.8
> $70,000	13.0
Decline to state	2.9
Ethnicity	
Caucasian	84.8
Native American	1.7
African American	3.4
Latino/Hispanic	7.2
Other	2.5
Decline to state	0.2

Fibromyalgia Impact Questionnaire (FIQ). The FIQ is a self-administered instrument developed to measure physical functioning and psychological, social, and global well being in patients with FM[25]. The first question lists 10 activities of daily living and makes up the physical functioning scale. Participants rate how often they were able to engage in each activity over the past week. Responses are on a 4 point Likert scale (always, most times, occasionally, and never). Overall physical functioning, from 0 to 3, was obtained by averaging all responses. The FIQ also contains seven 100 mm anchored visual analog scales (VAS) to measure fatigue, sleep quality, stiffness, anxiety, pain, work interference, and depression. Participants were asked to mark a point on the scale that best described how they felt over the past week. The marks are measured from 0 to 100 mm. Zero indicates no effect and 100 indicates severe effect. Each of the 10 items is scored on a 10 point scale. The item responses are then summed for a total score ranging from 0 to 100.

Center for Epidemiologic Studies Depression Scale (CES-D). The CES-D is a self-administered measure of depression used in general population surveys[26]. A 4 point Likert scale (0 = rarely or none of the time, and 3 = most or all of the time) is used to assess the frequency of 20 symptoms over the past week. The items are summed for an overall score from 0 to 60.

Pittsburgh Sleep Quality Index (PSQI). The PSQI assesses sleep quality over the past month. Questions cover a variety of factors including estimates of sleep duration, latency, frequency of disturbance, and severity of sleep related problems to generate a global sleep quality score. The PSQI has good test–retest reliability (r = 0.85) and internal consistency (alpha = 0.83), and effectively distinguishes "good" sleepers from "bad" sleepers[27].

Self-rated health. In addition to the standardized scales, patients rated their own health using the categories excellent, very good, good, fair, and poor. The measure was scored as an ordinal scale with excellent assigned the value 5 and poor assigned 0.

RESULTS

As a general measure of health status, the QWB scale generates a single number for each patient. This number can be used in several ways. Data from the QWB are often used in a methodology known as quality adjusted survival analysis. Using this method, survival time is adjusted by health related quality of life. In traditional survival analysis an individual is scored 1.0 if alive and 0.0 if dead. Adjusted survival analysis assigns wellness scores between 0.0 and 1.0 based on health related quality of life. The mean QWB score for the patients was 0.559 (SD 0.074). This suggests that for each year the average patient has FM, he or she loses the equivalent of 0.441 (calculated as 1.00 – 0.559 = 0.441) QALY.

Table 2 shows QWB scores for patients with FM in relation to other groups that have been studied using the QWB. The table shows that the effect of FM is quite profound. Scores for patients with FM are lower than for patients with endstage cancer, human immunodeficiency virus disease, and chronic obstructive pulmonary disease. They are comparable to patients with age related macular degeneration.

Table 3 summarizes mean FIQ scores along with self-rated health, CES-D, and PSQI. CES-D scores for this group tended to be high (mean 19.82, SD 11.39). The CES-D scores can range from 0 to 60, and nearly the entire range was observed in this patient sample (range 0–57). Scores > 18 on the CES-D suggest suspected clinical depression, and 50% of the patients in this sample scored at or above this threshold.

Table 3. Means and standard deviations for self-rated health, FIQ, CES-D, and PSQI.

Variable	Mean	SD
Self-rated health status	3.22	0.928
Physical functioning (FIQ)	1.31	0.711
How tired have you been (FIQ VAS)	76.54	21.43
How have you felt when you wake up (FIQ VAS)	76.95	22.43
How bad has your stiffness been (FIQ VAS)	70.11	24.19
How tense, nervous, or anxious (FIQ VAS)	49.65	29.84
How depressed or blue (FIQ VAS)	40.95	30.22
How bad has your pain been (FIQ VAS)	63.99	22.42
Total FIQ	61.23	16.08
CES-D	19.82	11.39
PSQI global	11.274	3.96

Table 4. Correlations of QWB and self-rated health status with FIQ and mental health measures.

Variable	QWB	Self-rated Health Status
Physical functioning (FIQ)	–0.571	–0.425
How tired have you been (FIQ VAS)	–0.300	–0.313
How have you felt when you wake up (FIQ VAS)	–0.260	–0.268
How bad has your stiffness been (FIQ VAS)	–0.288	–0.281
How tense, nervous, or anxious (FIQ VAS)	–0.274	–0.274
How depressed or blue (FIQ VAS)	–0.280	–0.274
How bad has your pain been (FIQ VAS)	–0.361	–0.327
Total FIQ	–0.488	–0.444
CES-D	–0.449	–0.420
PSQI global	–0.339	–0.292

All correlations are significant at $p < 0.001$.

Table 4 shows correlations between the QWB and other

Table 2. Mean QWB score by patient group.

Condition	Mean QWB	Reference
Well children	0.89	Kaplan, *et al*, 1976[5]
General population, San Diego	0.81	Kaplan, *et al*, 1976[5]
Elderly men, Beaver Dam, Wisconsin	0.68	Fryback, *et al*, 1993[28]
Elderly women, Beaver Dam, Wisconsin	0.67	Fryback, *et al*, 1993[28]
Adults with COPD	0.66	Kaplan, *et al*, 1984[29]
Osteoarthritis	0.64	Cronan, *et al*, 1997[30]
Depression (inpatients)	0.64	Pyne, *et al*, 1997[31]
Advanced cancer (site varied)	0.63	Anderson, *et al*, 1998[32]
AIDS patients in clinical trial of AZT	0.61	Kaplan, *et al*, 1989[8]
Macular degeneration	0.58	Williams, *et al*, 1998[33]
Fibromyalgia	0.56	This study
Alzheimer's disease	0.51	Kerner, *et al*, 1998[34]
Major non-head trauma	0.46	Holbrook, *et al*, 1994[35]

COPD: chronic obstructive pulmonary disease.

measures. The QWB was substantially correlated ($p < 0.001$) with the FIQ and with all other visual analog, sleep, and mental health measures. Self-rated general health status showed a similar pattern of correlations.

DISCUSSION

Data from patients with FM support the construct validity of a general QWB scale. For the measure to be useful for cross-illness comparisons, it is important that it shows validity for various specific disease populations. The general QWB scale was significantly associated with measures of physical functioning, pain, stiffness, anxiety, sleep, and depression. These variables were selected for study because of their presumed relationship with quality of life.

Data from this study suggest that the average patient with FM is in an objective state of functioning that is rated by community peers as about 0.56 on a 0 to 1.0 scale. If the person remains in that state for one year, he or she would have lost the equivalent of 44/100 of one year of life. Suppose that a new drug can improve functioning slightly and elevate QWB scores from 0.56 to 0.66. Over the course of one year, the patient would gain 0.10 QALY. If the benefit was maintained over 10 years, one QALY would be gained. Or, for each 10 patients who received a 0.10 benefit for one year, one QALY would be gained.

Since QWB scores are comparable across different patient groups, the QWB is valuable as a general outcome measure. For example, medical interventions in diverse disease states can be directly compared in cost utility analyses. Such direct comparisons are not possible using disease-specific measures. By assessing outcomes with a general measure such as the QWB, it is possible to compare directly the public health effect of treatments for FM with the effect of any other medical treatment. The QWB may therefore be especially useful in clinical trial assessment and estimates of a procedure's effect on a disease group. Using the QWB in FM treatment trials could help inform public policy by providing useful quality of life data on the effect of a given treatment in preventing or delaying the onset, or reducing the symptoms, of FM.

There are some important limitations with these data. Most important, the participants were volunteers from a single HMO in one metropolitan area. We do not know if they are representative of all patients with FM. Thus, the mean QWB score for these patients could be significantly different from the mean for all patients who carry this diagnosis. Several directions for future research should be considered. First, it will be important to replicate these results on a larger and more representative sample of patients with FM. Another direction will be to use the QWB to evaluate the cost effectiveness of both behavioral and pharmacological interventions for the treatment of FM. Longitudinal studies that track changes in quality of life over time are also needed. Finally, methodological studies evaluating the responsiveness of generic and disease-specific measures are needed.

ACKNOWLEDGMENT

We thank Kaiser Permanente for their cooperation and assistance in conducting this study and the research assistants and participants who made the study possible.

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