The Quality of Life Scale (QLS) for Schizophrenia: Assessment of Responsiveness to Clinical Change

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OBJECTIVE

The Quality of Life Scale (QLS) was developed to fill an important gap in the range of instruments available to measure symptom manifestation and treatment response in persons with schizophrenia. Heinrichs et al.[1] evaluated psychometric characteristics for cross-sectional validity and reliability, but not for longitudinal validity (or responsiveness). In order to assess this property, outcomes of the QLS should be calibrated to other more well-known and more interpretable measures of schizophrenia. This paper evaluates the responsiveness of the QLS to changes in patients' BPRS scores over time, and to clinician perceptions of changes in patients' severity of illness as measured by a clinical global impression (CGI) scale. Due to a variety of observed changes in BPRS total scores in the literature, we will examine responsiveness of the QLS to changes at 20%, 30%, 40%, and 50% decrease from baseline to endpoint.

METHODS

Patient Population

Both male and female patients who were at least 18 years of age were recruited from 174 sites. Patients were both inpatient and outpatient, and met the DSM-III-R criteria for schizophrenia, schizophreniform disorder, or schizoaffective disorder, and were randomly assigned to treatment in an international, multicenter double-blind trial to assess the efficacy of olanzapine and haloperidol in the treatment of schizophrenia. To be eligible, patients were required to have a minimum score of 18 on the Brief Psychiatric Rating Scale (BPRS).[2]

For purposes of this analysis, only patients completing both a baseline and a six-week observation for which a QLS change score could be computed were included.

Measures

The Quality of Life Scale (QLS)[1]

The QLS was developed to assess symptoms in the course and treatment of schizophrenia. It is a 21-item clinician rating scale based on a 30- to 45-minute semi structured interview providing information on symptoms and functional status during the preceding four weeks. Based on a conceptual framework, the scale items were derived from consideration of important manifestations of the deficit syndrome in schizophrenia. The measure is scored into the following four categories: Intrapsychic Foundations (7 items), Interpersonal Relations (8 items), Instrumental Role (4 items), Common Objects and Activities (2 items), as well as an overall score. Acceptable psychometric criteria has been reported.[1]

The Brief Psychiatric Rating Scale (BPRS)[3]

The primary purpose for developing the BPRS interview was to obtain a highly efficient, rapid evaluation procedure for use in assessing treatment change in psychiatric patients while at the same time yielding a comprehensive description of major symptom characteristics. It consists of a Total Score, a Positive Scale (4 items), a Negative Scale (3 items), and an Anxiety and Depression Scale (4 items). A normalized scoring system is used based on the following scale: 0: Absent, 1: Minimal, 2: Mild, 3: Moderate, 4: Moderate/Severe, 5: Severe, and 6: Extreme. The BPRS is an accepted method of assessing general psychopathology as well as positive and negative symptoms in patients with schizophrenia.

Clinical Global Impression (CGI): Severity of Illness[4]

CGI scales are frequently used in clinical trials to rate severity of illness. The CGI score is based on a clinician's assessment of how mentally ill the patient is at the current time on a 1 to 7 scale (1: Normal, not at all; 2: Borderline ill; 3: Mildly ill; 4: Moderately ill; 5: Markedly ill; 6: Severely ill; 7: Among the most extremely ill patients). When administering the CGI-severity of illness, interviewers focused their attention on the following psychiatric diagnoses: schizophrenia, schizophreniform disorder, and schizoaffective disorder (bipolar type or depressive type).

1 Heinrichs, D.W.; Hanlon, T.E.; and Carpenter, W.T. The Quality of Life Scale: an instrument for rating the schizophrenic deficit syndrome. *Schizophrenia Bulletin*, 10:388-398, 1984.
2 Tollefson, G.D.; Beasley, C.M.; Tran, P.V.; Street, J.S.; Krueger, J.A.; Tamura, R.N.; Graffeo, K.A.; and Thieme, M.E. Olanzapine versus haloperidol in the treatment of schizophrenia and schizoaffective disorder and schizophreniform disorders: results of an international collaborative trial. *American Journal of Psychiatry*, 154:457-65, 1997.
3 Overall, J.E., and Gorham, D.R. The Brief Psychiatric Rating Scale. *Psychological Reports*, 10:799-812, 1962.
4 Guy, W. *ECDEU Assessment Manual for Psychopharmacology, revised*. DHEW Pub. No. (ADM) 76-338, Rockville, MD: National Institute of Mental Health, 1976.

RESULTS

Table 1. Baseline Characteristics of the Patients (n=686)

Age – yr	38.5 ± 11.3
Male sex – no. (%)	462 (67.3)
Race or ethnic group – no. (%)	
White	506 (73.8)
Black	104 (15.2)
Hispanic	45 (6.6)
Other	31 (4.4)
Illness Type – no. (%)	
Schizophrenia	578 (84.2)
Schizoaffective disorder	104 (15.2)
Schizophreniform disorder	4 (0.6)
Age at onset of schizophrenia – yr	23.6 ± 7.7
BPRS Scores	
Total Score	31.8 ± 10.4
Negative	6.5 ± 3.3
Positive	9.7 ± 3.9
Anxiety & Depression	7.5 ± 3.6
Quality of Life Scores	
Total Score	51.5 ± 20.7
Intrapsychic Foundations	19.5 ± 7.4
Interpersonal Relations	18.6 ± 9.3
Instrumental Role	6.9 ± 6.1
Common Objects & Activities	6.6 ± 2.6
Clinician Global Impression	4.5 ± 0.9

Table 2. Response Rates

BPRS Scores	No. improved (cumulative)	%
BPRS Total score (n=686)		
20% or greater improvement	542	79.0%
30% or greater improvement	475	69.2%
40% or greater improvement *	389	56.7%
50% or greater improvement	295	43.0%
BPRS Negative Scale (n=658)		
20% or greater improvement	440	66.9%
30% or greater improvement	372	56.5%
40% or greater improvement	306	46.5%
50% or greater improvement	263	39.9%
BPRS Positive Scale (n=681)		
20% or greater improvement	528	77.5%
30% or greater improvement	460	67.5%
40% or greater improvement	382	56.1%
50% or greater improvement	312	45.8%
BPRS Anxiety/Depression Scale (n=677)		
20% or greater improvement	504	74.4%
30% or greater improvement	455	67.2%
40% or greater improvement	403	59.5%
50% or greater improvement	339	50.1%

* Patients showing a 40% improvement were considered as having a clinical response

Figure 1: QLS Total Score Improvements by Changes in BPRS Total Score

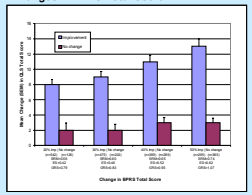


Figure 2: QLS Instrumental Role Score Improvements by Changes in BPRS Total Score

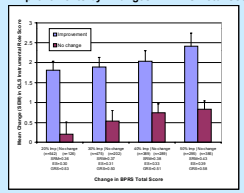


Figure 3: QLS Common Objects & Activities Score Improvements by Changes in BPRS Total Score

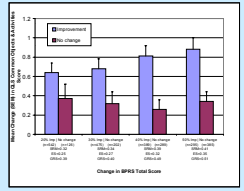


Figure 4: QLS Intrapsychic Foundations Score Improvements by Changes in BPRS Total Score

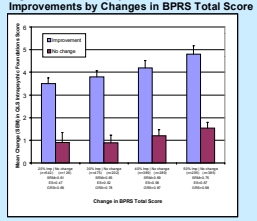


Figure 5: QLS Interpersonal Relations Score Improvements by Changes in BPRS Total Score

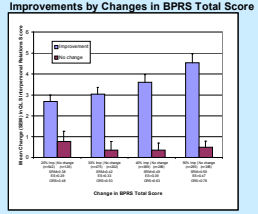
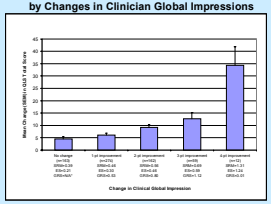


Figure 6: QLS Total Score Improvements by Changes in Clinician Global Impressions



* This is the stable group, so GRS could not be calculated.

CONCLUSION

As an outcomes measure for clinical trials, use of the QLS could allow the impact of schizophrenia-specific symptomatology on patient QOL to be a possible determinant in evaluating therapeutic interventions, and describing the course of illness. The challenge with measures of quality of life is how to translate the data into clinically meaningful terms. We have analyzed data from a large, randomized clinical trial assessing schizophrenic treatment to assess the utility of this scale to detect small but clinically meaningful changes. The majority of participants in this subsample showed improvement in QLS scores that correlated with both clinical measures of change: disease-specific (BPRS) and overall rating of change (CGI). Over the six-week treatment period, a 20% improvement in the QLS total score was noted in 39% of the population. One of the strengths of this study was the use of varying levels of change in BPRS scores to indicate clinical improvement. Over one-half of the population (56.7) achieved a response rate of 40% or greater reduction (improvement) in BPRS total score. Results showed strong trends toward improvement in QLS scores (6, 7, 8, and 10 points) with each level of improvement in schizophrenia symptomatology (20, 30, 40, and 50%, respectively). A 26.4% improvement in the clinical global impression score of the overall population was seen in this analysis. Individual CGI improvements of 1-pt., 2-pts., 3-pts., and 4-pts. were associated with improvements in QLS scores of 2, 5, 9, and 30 points, respectively. Based on these results, it could be concluded that the minimal clinically important difference for the QLS ranges between 2 points (corresponding to a 1-point improvement on the CGI) to 6 points (corresponding to a 20% improvement in BPRS total scores) with responsiveness statistics ranging from 0.3 to 0.8.

Evaluation of the QLS subscales showed Intrapsychic Foundations to be the most sensitive to changes in BPRS total scores. The content of this subscale focuses primarily on dimensions that reflect the patients' sense of purpose, motivation, empathy, ability to experience pleasure, and emotional interaction. As these capacities are viewed as the building blocks from which interpersonal and instrumental role functioning are derived, it is not surprising to see this subscale demonstrate the greater degree of responsiveness in patients with this condition.

Parallel use of the QLS over time with disease-specific and overall rating of change measures demonstrates the ability of the QLS to detect clinically meaningful change.