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Assessment of the minimum clinically important difference in quality of life in schizophrenia measured by the Quality of Well-Being Scale and disease-specific measures



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ABSTRACT

This study examines the psychometric properties of the Quality of Well Being Scale (QWB), the Positive and Negative Syndrome Scale (PANSS), the Heinrich-Carpenter Quality of Life Scale (QOLS), and the Lenert PANSS-based utility measure in a cohort of patients with schizophrenia and identifies threshold values of clinically meaningful change using the Clinical Global Impressions scale (CGI), as the anchor. The correlation of these measures at baseline and change at 6 and 12 months post enrollment in a comparative effectiveness trial was evaluated in 350 veterans with schizophrenia or schizoaffective disorder. An equipercentile method was used to estimate the minimum clinically important difference (MCID) for each measure. Effect size of 0.30–0.50 for baseline quality of life associated with inpatient status supported concurrent validity. The QWB was moderately correlated with disease-specific measures. The MCID as detected by the CGI at 6 months was 0.17 for QWB, 0.15 for the Lenert utility score, 1.13 for the QOLS, and 20.2 for the PANSS. These differences were stable at 12 months. The QWB is significantly correlated with disease specific measures of health related quality of life in schizophrenia.

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1. Introduction

Cost-effectiveness analysis of health care interventions requires outcomes to be expressed in Quality Adjusted Life Years (QALYs), a measure of morbidity adjusted survival (Gold et al., 1996). The quality of life measure must be preference-based, interval scaled, and use reference points of zero for death and one to represent optimal health. This method allows both benefits and side effects of interventions to be weighed in a single scale that can be used across the spectrum of disease (Gold et al., 1996; Kaplan et al., 2004).

Assessment of preference based quality of life (utility) in schizophrenia, perhaps the most devastating of psychiatric disorders, has received limited study. One of the most promising measures for use in this disorder is the Quality of Well-Being Scale (QWB) (Pyne

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et al., 2003). QWB scores were substantially lower in patients with schizophrenia than in normal controls and lower QWB scores were significantly correlated with psychosis symptom scores and severity of depression (Patterson et al., 1996, 1997). QWB scores were lower in patients with poorer positive and general psychopathology subscales of the Positive and Negative Syndrome Scale (PANSS), the most commonly used measure of symptom severity in schizophrenia (Kasckow et al., 2001). QWB scores were also more sensitive to change in psychosis symptoms than other quality of life measures in a population of inpatients with schizophrenia (Pyne et al., 2003). Since QWB and other preference-based methods assessments are not widely used in studies of schizophrenia, Lenert and colleagues developed a method to translate disease-specific measures from the PANSS and side effect indicators into utility (Lenert et al., 2005). Estimates based on this method have not yet been compared to the OWB.

Correlation between measures, while an indicator of concurrent validity, is not, in itself, an indicator of clinically meaningful change. The concept of the Minimum Clinically Important Difference (MCID)

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has emerged as the principal way of giving clinical relevance to changes in standardized measures. The MCID has been defined as "the smallest difference in a score in the domain of interest which patients [or providers] perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a meaningful change in the patient's management (Jaeschke et al., 1989)." There is no widely accepted means to estimate the MCID (Pouchot et al., 2008; Liang et al., 2002).

Anchor based methods have been considered for determining MCIDs in patients with schizophrenia (Cramer et al., 2001; Rabinowitz et al., 2006; Leucht et al., 2005; Levine et al., 2008; Schennach-Wolff et al., 2010; Hermes et al., 2012; Lydick and Epstein, 1993). These methods use a measure with established or face-value clinical meaning such as the Clinical Global Impressions Severity Scale (CGI-S) for cross-sectional assessment or the Clinical Global Impressions Improvement scale (CGI-I) for improvement over time to anchor scores on the measure of interest (Guy, 1976).

In a validation of the QWB in medical illness, cases with differences in scores of less than 0.03 could not be differentiated by judges and a utility score of 0.03 was thus assumed to represent the MCID on the QWB (Kaplan, 1993). A comparison of several methods found the MCID of the QWB was between 0.014 and 0.058 in a population with chronic pulmonary disease (Kaplan et al., 2004). However, no study as yet evaluated the MCID for the QWB in individuals with schizophrenia using a technique anchored to a face-value clinical assessment.

We used data from a clinical trial of long-acting injectable (LAI) and oral medications for patients with schizophrenia in the Veterans Affairs (VA) healthcare system to: (1) compare the sensitivity and responsiveness on the QWB and commonly used disease-specific measures to differences in quality of life in inpatient and outpatients at the time of entry into the trial, (2) examine the correlation of the QWB both cross sectionally and longitudinally with the disease specific measures, and (3) identify a threshold value of clinically meaningful change for QWB and other measures by linking changes at 6- and 12-months in these measures with clinical ratings of improvement on the CGI.

2. Methods

The VA Cooperative Study on Long-Acting Injectible Risperidone in the Treatment of Schizophrenia was a randomized clinical trial comparing oral antipsychotics to LAI Risperidone in the treatment of VA patients with clinically unstable schizophrenia. The trial design and subject recruitment procedures have been previously reported (Rosenheck et al., 2011). The trial enrolled 369 adult veterans diagnosed with schizophrenia or schizoaffective disorder confirmed by the Structured Clinical Interview (First et al., 1996) who had been hospitalized in the previous 2 years or were in imminent need of hospitalization. They were randomized to receive either LAI Risperidone or to continue their current oral antipsychotic therapy. Randomization began in September 2006, and subjects were recruited over a 3 year period allowing for up to 2 years of follow up. Hospitalization status at time of randomization (inpatient vs. outpatient) was ascertained with VA administrative data and patient reports of non-VA hospitalizations validated by review of discharge summaries. Blinded videoconference assessments were conducted every 3 months to collect data on measures of symptoms and quality of life, and un-blinded ratings by the study nurse were conducted monthly to assess global clinical mental health status and global clinical improvement since the beginning of the study using measures described below. Patients also completed the self-report version of the QWB. This paper reports on study participants who completed a baseline assessment of health related quality of life using data gathered at enrollment and 6 and 12 months after randomization

2.1. Measures

2.1.1. Schizophrenia-specific measures

Symptoms of schizophrenia were measured according to the total score on PANSS, and its positive, negative, and general subscales (Kay et al., 1987). Scores range from 30 to 210, with higher scores indicating more symptoms. Quality of life was measured with the Heinrichs–Carpenter Quality of Life Scale (QOLS), a rater-

based measure commonly used in trials of medications for schizophrenia (Heinrichs et al., 1984). Twenty items are rated on 0–6 point scales according to well-defined anchors and averaged with higher scores representing better quality of life.

QOLS and PANSS ratings were obtained from videoconference interviews conducted by trained raters from MedAvante Inc. who were unaware of the patients' study drug assignments. Psychiatric assessments by video conference have been shown to be reliable in patients with schizophrenia and are well received (Ruskin et al., 1998).

2.1.2. Preference based health related qualify of life

Utilities were assessed by the QWB. The trial used the self-report version which is based on 18 dichotomous and 53 four-level items. Respondents were asked the number of days in the past three days in which various health and functional problems were experienced. These items were used to calculate utility using a previously developed algorithm, based on a scale ranging from 0 to 1, representing states from death to perfect health (Kaplan and Anderson, 1996). An independent estimate of utility was generated using PANSS ratings and indicators of medication side-effects, using the disease-specific algorithm developed by Lenert et al. (2005).

2.1.3. Global mental health status

The CGI-I was used to assess the change in clinical status. These scales use a higher score to indicate poorer functioning or less improvement (Guy, 1976). The improvement scale, CGI-I has 7 possible values: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse.

2.2. Analysis

The validity of all measures was evaluated by comparing baseline assessments of subjects who were hospitalized at enrollment (inpatients) to those not hospitalized (outpatients) assuming that hospitalized patients would be more severely ill and functionally impaired. Analysis of variance was used to determine if the mean utility scores were significantly different between the inpatient and outpatient subgroups. Effect size was calculated as the difference in mean score between inpatient and outpatient samples divided by pooled standard deviations.

Inter-measure correlations were assessed in the overall sample using the Pearson correlation between baseline measures at enrollment.

For those with 6 month follow up assessments (N=255, 73%) and 12 month assessments (N=224, 64%), change score was computed as the follow up score minus the baseline score. For PANSS and its subscales, both higher score and positive change represents poorer health, while for the QOLS and utility measures, the higher score and positive change represents better health. The Pearson correlations were computed to evaluate the relationship between change in measures after 6 months of follow up.

We used the equipercentile linking method first described by Kolen and Brennan (1995) and adapted for SAS program by Price et al. (2001) to compare in a pair-wise fashion, changes in utility and disease specific measures that correspond with CGI-I ratings at 6 and 12 months. We assumed that a one unit difference in the CGI-I represent the MCID. By establishing CGI-I as an anchor, the amount of change in the measure that corresponds in percentile rank to a one unit change in the CGI-I is interpreted as the MCID. The application of the equipercentile linking method to CGI-I ratings has been previously used in several studies to evaluate the MCID of the PANSS in schizophrenia (Leucht et al., 2005; Levine et al., 2008; Schennach-Wolff et al., 2010). The average MCID across the full range of the CGI-I was calculated by dividing the range of change scores on the measure of interest by 6 (the number of intervals between CGI-I levels), using internal weights based on observations within each level.

3. Results

Of the 369 veterans enrolled in the trial, 350 subjects (95%) had complete baseline assessment on the measures used in this study (CGI, QWB, LENERT, PANSS and QOLS); 138 subjects (39%) were enrolled as inpatients and 212 (61%) as outpatients.

The study population was primarily male, with an average age of 50.7 years (S.D. 9.3), 9% of Hispanic ethnicity, 45% White, and 48% African American (Table 1). Baseline PANSS scores averaged 79.69 indicating highly symptomatic illness; utility scores of 0.60 (by QWB) and 0.68 (by the Lenert method) reflected poor overall health and QOLS scores of 2.57 indicated substantial dysfunction.

Utility and other measures significantly differentiated inpatient and outpatient subjects at time of enrollment with moderate effect sizes of approximately 0.30–0.50, suggesting consistent concurrent validity of the measures (Table 2).

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