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Reliability of a patient-reported outcome measure in schizophrenia: Results from back-to-back self-ratings

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ABSTRACT

This study aimed to assess patient's capacity to perform a patient-reported outcome (PRO) measure (i.e., a self-rating scale) and examine its relationship with clinical characteristics including cognition. Fifty patients with schizophrenia were asked to rate the Subjective Well-being under Neuroleptics scale – Short form (SWNS) twice; the second rating was started immediately after they completed the first to minimize the gap between ratings. At the same time, the Positive and Negative Symptoms Scale (PANSS) and Brief Neurocognitive Assessment (BNA) were administered. The correlations between the two ratings for the SWNS total and each item scores were high (r_s=0.94 and r_s=0.60–0.84, respectively); however, for 16 (80%) of 20 items, 5 or more patients (i.e., ≥10%) demonstrated a >1 point score difference. There was no significant correlation between the SWNS total score difference and any clinical characteristics including age, education duration, illness duration, antipsychotic dose, psychopathology, and cognition. In contrast, the number of items with a >1 point score difference was significantly correlated with disorganized symptoms and overall severity (r_s=0.29 for both), as well as working memory and global cognition (r_s=−0.41 and r_s=−0.40, respectively). These findings suggest that PROs should be interpreted with caution in patients with schizophrenia with prominent disorganization and cognitive impairment.

1. Introduction

Patient-reported outcomes (PROs), defined as "any report of the status of a patient's health condition that comes directly from the patient" by the United States Food and Drug Administration, have increasingly taken on a role in clinical research in schizophrenia, paralleling a growing interest in recovery (Reininghaus and Priebe, 2012). Arguably, self-rated measures may be considered more reliable than clinician-rated measures, and they circumvent the issue of interrater variability (McCabe et al., 2007). However, patients with schizophrenia can demonstrate poor self-recognition performance (Waters et al., 2012) and poor cognitive impairment associated with poor insight into illness (Nair et al., 2014), limiting their capacity to perform self-rating scales. This, in turn, may hinder the value of PRO measures.

Test-retest reliability is used to endorse intrasubject reliability for self-rating scales (Cavelti et al., 2012; Huizinga and Elliott, 1986), with the interval between testing ranging from weeks to months. However, the question of whether patients are consistent in their self-ratings has not received much attention, and one means of assessing this is to compare ratings carried out back to back to minimize the gap between ratings. To our knowledge, however, there have been no studies to examine test-retest reliability of PRO measures with back-to-back ratings in psychiatric disorders.

The Subjective Well-being under Neuroleptics scale (SWN) (Naber, 1995) and its short form, (SWNS) (Naber et al., 2001), represent one of the most widely used PRO measures in clinical studies in schizophrenia (Vothknecht et al., 2011). The original scale was developed to capture subjective well-being during antipsychotic treatment (Naber et al., 1995), and the scale has since been translated to various languages. In the present study, we utilized this scale to assess patients' capacity to perform a PRO measure (i.e., a self-rating scale) back to back, comparing the two scores and their relationship with clinical characteristics including cognition.

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2. Material and methods

2.1. Study design

This cross-sectional study was conducted at the Centre for Addiction and Mental Health (CAMH) in Toronto, Canada from June to November 2015, and approved by the CAMH Research Ethics Board. After full description of the study, all participants provided written informed consent prior to study entry.

Patients with schizophrenia or schizoaffective disorder, aged 18 years or older, were included in this study. The following scales were administered: Positive and Negative Symptoms Scale (PANSS) (Kay et al., 1987); Brief Neurocognitive Assessment (BNA) (Fervaha et al., 2015, 2014); and Subjective Well-being under Neuroleptics scale – Short form (SWNS) (Naber et al., 2001). Also, basic demographic information including age, sex, duration of illness, duration of education, and current medications was collected.

The SWNS is a self-rating scale that consists of 20 items, with each item score ranging from 1 to 6 to capture subjective well-being under antipsychotic treatment. The SWNS were constituted by five subscales (i.e., mental functioning, self-control, emotional regulation, physical functioning, and social integration), each of which includes four items. Patients are asked to make ratings based on the prior week and the total score ranges from 20 to 120, a higher score indicating better subjective well-being. Half of the items are described in the form of a positive statement and the other half as a negative statement. Participants were asked to rate the SWNS twice; the second rating was started immediately after the first was completed. Because ratings are based on patients' subjective well-being over the past week, theoretically there should be no change in responses over such a short timeframe.

2.2. Statistical analyses

To quantify the gap between the two self-ratings, correlation analyses and paired *t*-tests were employed for total and each item scores, and the number of patients who demonstrated a >1 point score difference was calculated for each item.

To examine the relationship between the gap in self-rating and clinical characteristics such as age, duration of education, duration of illness, antipsychotic dose, psychopathology, and cognition, correlation analyses were performed using the total score difference and the number of items with a >1 point score difference. When computing the total score difference between the two ratings, an absolute value was used (i.e., a minus value was converted to a plus value) since the focus of the analysis was to identify clinical factors related to the magnitude of difference between two self-ratings. Chlorpromazine equivalent antipsychotic dose was calculated according to Gardner et al. (2010); because it was not available in this reference, paliperidone long-acting injection 75 mg/month is considered equivalent to risperidone long-acting injection 37.5 mg/2 weeks (WHO Collaborating Centre for Drug Statistics Methodology, 2016). The following five PANSS factor scores were calculated according to the consensus PANSS five-factor model (Wallwork et al., 2012): positive, disorgaized, negative, excited, and depressed factors. From the BNA, scores of the symbol-coding and letter-number span tests were converted to age- and sex-matched standardized *Z* scores. The global *Z* score was computed based on the two *Z* scores.

All the analyses were also performed for each of five subscales; however, since our primary interest was in the total and item scores, these results were considered secondary and exploratory.

Spearman's rank correlation coefficients were calculated for all correlation analyses. A two-tailed *P*-value of <0.05 was considered statistically significant for all tests. All statistical analyses were conducted using the IBM SPSS Statistics version 21 (IBM Corporation, Armonk, NY).

3. Results

A total of 50 outpatients participated in the study; the demographics and clinical characteristics are shown in Table 1. The mean SWNS total scores were above 80 at both time points, with 37 patients (74%) and 34 patients (68%) scoring 80 or higher at the first and second time, respectively, indicating the majority of the participants had adequate subjective well-being according to the definition in previous studies (Lambert et al., 2009, 2007, 2006).

3.1. Differences in two ratings of SWNS

Spearman's rank correlation coefficient between the two ratings for the total scores was as high as 0.94, and no significant difference in the total scores was found between the two ratings (Table 2). Two scores were significantly correlated for all five subscales ($r_s=0.37$–0.92); there was a significant difference in the scores between the two ratings only in mental functioning ($P=0.02$).

Spearman's rank correlation coefficients between the two ratings for each item ranged from 0.60 to 0.84, reflecting good correlations (Table 2). In addition, paired *t*-tests revealed a significant difference in scores between the two ratings for only one item (item 12, "My feelings and behavior are inappropriate to situations. I get upset over small things, important ones hardly affect me."). However, for 16 (80%) of 20 items 5 or more patients (i.e., $\geq 10\%$) demonstrated a >1 point score difference.

Figs. 1 and 2 illustrate the distribution of the SWNS total score differences and the number of the SWNS items with >1 point score difference, respectively. The identical total scores were observed in only 4 patients (8%), and improved and worsened scores were noted in 27 patients (54%) and 19 patients (38%), respectively. In only 11 patients (22%), all 20 items were rated within a 1 point score difference between the two ratings.

Table 1
Demographics and clinical characteristics of patients (N=50).

	Mean (*SD*) or N (%)	Range
Age, years	41.1 (12.6)	21–66
Male	30 (60.0)	NA
Duration of education, years	13.1 (2.2)	8–19
Diagnosis		
Schizophrenia	39 (78.0)	NA
Schizoaffective disorder	11 (22.0)	NA
Duration of illness, years	18.0 (11.5)	1–43
Antipsychotic dose (chlorpromazine equivalent), mg/day	571 (293)	0–1500
PANSS total	69.6 (25.8)	33–123
BNA, *Z* score[a]		
Symbol-coding	−1.32 (1.19)	−4.26 to 1.08
Letter-number span	−1.08 (1.31)	−4.87 to 0.78
Global	−1.42 (1.32)	−5.70 to 0.85
SWNS		
Total at 1st time	88.6 (14.6)	46–114
Total at 2nd time	89.6 (17.3)	46–120
Total score difference	4.9 (3.8)	0–13

Abbreviations: BNA, Brief Neurocognitive Assessment; CGI-S, Clinical Global Impression – Severity of Illness; PANSS, Positive and Negative Syndrome Scale; PSP, Personal and Social Performance scale; SWNS, Subjective Well-being under Neuroleptics scale – Short form.

[a] Age- and sex-matched standardized *Z* score.