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Title: Responsiveness of the Personal and Social Performance scale in patients with

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Abstract

The responsiveness (ability to detect change) of the Personal and Social Performance scale (PSP) is largely unknown, limiting its use as an outcome measure. The purpose of this study was to examine both internal and external responsiveness of the PSP in patients with schizophrenia in the acute phase. Eighty patients were administered the PSP and the Clinical Global Impression-Severity scale (CGI-S) at admission and at discharge. We used the standardized effect size, the standardized response mean, and paired t-test for examining internal responsiveness. We examined the correlations between the changes in scores of the PSP and those of the CGI-S using Pearson's r for validating the external responsiveness. The results showed that the standardized effect sizes and standardized response means of the PSP were 0.74-1.74 and 0.68-1.72, respectively. The paired t-tests showed statistically significant difference (p<0.001). Moderate to good correlations (r=0.35-0.74) were found among the changes of the PSP with those of the CGI-S. The PSP showed substantial internal responsiveness and sufficient external responsiveness in patients with schizophrenia receiving treatment in the acute phase. The PSP appears useful as an outcome measure for detecting changes of social functioning over time.

Keywords: social functioning; schizophrenia; responsiveness

1. Introduction

Social dysfunction is a core feature in patients with schizophrenia (Burns and Patrick, 2007). Patients with schizophrenia who have social dysfunction impede patients' performance in self-care, interpersonal relationship, and work function and gradually impose great burdens on their family members and the society (Shi et al., 2013). Improving social functioning has been seen as one of the important goals in the treatment for patients with schizophrenia in clinical and research settings (Bai et al., 2014). Therefore, using an appropriate outcome measure is critical to monitor changes in social functioning in patients with schizophrenia.

The Personal and Social Performance scale (PSP) is frequently used to assess social functioning in patients with schizophrenia. The PSP has clear operational instructions for rating the severity of disability. The PSP contains four domains: (1) socially useful activities; (2) personal and social relationships; (3) self-care; and (4) disturbing and aggressive behavior. It provides multidimensional concepts of social functioning. Clinicians and researchers are able to decide patients' weaknesses and strengths in different domains of social functioning. Moreover, the PSP has a global score according to the ratings from the four domains, which represents overall social functioning (Morosini et al., 2000). Therefore, the contents of the

PSP appear appropriate for assessing social functioning in patients with schizophrenia (Burns and Patrick, 2007; Jelastopulu et al., 2014; Rocca et al., 2014).

To determine the utility of an outcome measure, evidence of psychometric properties (i.e., reliability, validity, and responsiveness) are required. The PSP has shown sufficient reliability and validity in different countries and settings for patients with schizophrenia (Brissos et al., 2012; Garcia-Portilla et al., 2011; Kawata and Revicki, 2008). However, the responsiveness (sensitivity to change) of the PSP has rarely been examined. Responsiveness is the ability of a measure to detect change (deterioration or improvement), which happens as a result of disease progression or receiving treatments (Tamanini et al., 2005). Two aspects of responsiveness are internal responsiveness and external responsiveness. Internal responsiveness refers to the ability of a measure to detect change over a pre-specified time frame, in which the trait assessed changes spontaneously over time or due to receiving treatments. External responsiveness refers to the extent of correlation between changes in a measure and change in a reference measure over a specified time frame (Husted et al., 2000). If the correlation is substantial, change in the measure is able to reflect patients' change in the reference measure (e.g., severity of psychiatric illness). It is critical to justify internal and external responsiveness of the PSP to ensure its utility in both research and clinical settings.

A few studies examined the responsiveness of the PSP in patients with schizophrenia (Garcia-Portilla et al., 2011; Nasrallah et al., 2008; Patrick et al., 2009). However, these

studies examined the responsiveness of the PSP using the global score, barely examining the responsiveness for each domain of the PSP. Moreover, three issues can be displayed in previous studies. First, about 23%-52% of patients showed stable illness severity (e.g., no change in the Clinical Global Impression-Severity scale [CGI-S] at baseline and follow-up) in the previous studies. For these studies with relatively high percentages of participants in the stable condition, it may be not easy to detect change of the PSP. Second, these previous studies examined responsiveness using patients with a 1-point change on the CGI-S at baseline and follow-up, but without estimating patients with a >1-point change on the CGI-S. The results of responsiveness in the PSP may be underestimated. Third, a few studies examined external responsiveness and the magnitude of correlations in scores of the PSP and those of the reference measure were not provided, which limits the explanations of external responsiveness. To examine responsiveness, further investigation is necessary to recruit patients with broader changes in illness severity at baseline and follow-up.

Therefore, the purpose of this study was to examine the internal and external responsiveness of the PSP for patients with schizophrenia in a comprehensive manner (including the global score and domain scores). We recruited patients with severe symptoms. In this study, the two hypotheses were as follows: (1) for internal responsiveness, the PSP has moderate to large effect size and the change scores of the PSP are statistically significant; and (2) for external responsiveness, the changes in scores of the PSP has moderate to good

correlations with those of the CGI-S.

2. Methods

2.1. Participants

We recruited a convenience sample, 80 inpatients with schizophrenia undergoing treatment from acute wards at one hospital between December 2014 and October 2015. Half of the patients were male and all of them were Asians (Taiwanese). The mean age of the patients was 43.1 years in this study. The mean onset age was 25.2 years. The average numbers of admissions before this treatment was 6.7. Regarding comorbidities, 15% and 10% of participants had hypertension and diabetes, respectively. 82.5% of patients were taking second generation antipsychotics, in particular clozapine, risperidone, and olanzapine and 27.8% of them were taking first generation antipsychotics, in particular haloperidol and flupentixol. Further characteristics of the patients, such as socioeconomic status according to the Hollingshead classification (Hollingshead and Redlich, 1958), are presented in Table 1.

Patients were included according to the following criteria: (1) diagnosis of schizophrenia based on the Diagnostic and Statistical Manual of Mental Disorders, fifth edition; (2) aged >20 years; and (3) signed the informed consent personally or by the surrogate. We excluded patients who had history of severe brain injury or were diagnosed with substance/medication-induced psychotic disorder or intellectual developmental disorder. This

study has obtained approval by the ethics committee from the Institutional Review Board of Taipei City hospital.

2.2. Procedure

Before administering the measures, one rater (i.e., nurse) who had >15 years of psychiatric clinical experience received at least 4 hours training. In the training, the rater needed to become familiarized with the concepts of the measures, response categories, and scoring. The rater was trained with two clinicians who used the PSP regularly at work and during the training session. They conducted semi-structured interviews on 12 patients. After the interviews with the patients, the rater and the two clinicians discussed any questions and disagreements until a > 0.8 intraclass correlation coefficient (ICC) was achieved for ascertaining the degree of reliability.

Patients who met the inclusion and exclusion criteria were assessed with the PSP and the CGI-S by the rater twice, after admission and at discharge. These two measures were administered in the first three days after admission to the acute wards and in the final three days before discharge from the hospital. Demographic data of the patients were collected from medical records.

2.3. Instrument

2.3.1. Personal and Social Performance scale

The PSP measures social functioning from four domains (Morosini et al., 2000). The socially useful activities domain assesses the social roles of performing housework, study, and work. The personal and social relationships domain assesses the social interactions and relationship with others. The self-care domain assesses basic activities of daily living. The disturbing and aggressive behaviors assesses whether patients have inappropriate social behaviors (e.g., verbal threats and physical assaults). Each domain is rated on a 6-point scale according to specific operational criteria to decide the severity of difficulties (1=absent, 2=mild; 3=manifest but not marked; 4=marked; 5=severe; and 6=very severe). A greater score represents severer specific domain function. Using the scoring algorithm (i.e., combination of the severity scores from the four domains), the four domain scores are transformed into a global score of social functioning. The global score is rated on a 100-point scale and ranged from 0 to 100. A higher global score represents better overall social functioning. Regarding the reliability of the PSP, the internal consistency (Cronbach's alpha = 0.79-0.84), test-retest reliability (ICC = 0.66-0.94) and inter-rater reliability (ICC = 0.43-0.95) has been examined (Brissos et al., 2012; Lee et al., 2016; Tianmei et al., 2011). For the content of the PSP, it was developed on a basis of the social functioning component of the Diagnostic and Statistical Manual of Mental Disorders, fourth edition, and the Social and Occupational Functioning Assessment Scale (SOFAS) (Morosini et al., 2000). The PSP

has shown sufficient convergent validity (Pearson' r = 0.95 among the PSP and the SOFAS), and discriminative validity (e.g., discriminating different levels of severity) in patients with schizophrenia (Garcia-Portilla et al., 2011; Nasrallah et al., 2008)."

2.3.2. Clinical Global Impression-Severity

The CGI-S measures severity of psychiatric illness using one item (Guy, 1976). The item is rated on the 7-point scale (1=normal; 2=borderline mentally ill; 3=mildly ill; 4=moderately ill; 5=markedly ill; 6=severely ill; and 7=among the most extremely ill patients). The convergent validity of the CGI, Pearson' r = 0.72-0.79 among the CGI-S and the Yong Mania Rating Scale-Depression and the Hamilton Rating Scale-Depression has been examined for patients with schizophrenia (Turkoz et al., 2013). The CGI-S was used as the external criterion for examining external responsiveness of the PSP.

2.4. Data analysis

2.4.1. Internal responsiveness

Two types of effect size (i.e., the standardized effect size and the standardized response mean) and paired *t*-test were used to examine internal responsiveness of the PSP during the period of admission to the acute ward and discharge from the hospital. The standardized effect size was calculated as the mean change scores between admission and discharge

divided by the standard deviation of admission score ($SD_{admission}$). The standardized response mean was estimated as the mean change scores in the two measurements divided by the standard deviation of score change (SD_{change}). The criteria of the standardized effect size and the standardized response mean were: < 0.50, small responsiveness; 0.50-0.79, moderate responsiveness; and \geq 0.80, large responsiveness (Husted et al., 2000). Paired t-test was used to determine whether the change scores were statistically significant in the two measurements of the PSP.

2.4.2. External responsiveness

We investigated external responsiveness between the changes in scores of the PSP and those of the CGI-S using Pearson's r. Correlation values of ≤ 0.30 were considered poor, values of 0.31-0.59 were considered moderate, and values of ≥ 0.60 were considered good (Andresen, 2000). A moderate correlation indicated sufficient external responsiveness.

2.4.3. Score distribution

We examined ceiling and floor effects for the score distribution. The ceiling effect was the percentage of participants with the highest score (i.e., score 6 in each domain and interval of 91-100 in the global score). The floor effect was the percentage of participants with the lowest score (i.e., score 1 in each domain and interval of 1-10 in the global score). Notable

ceiling and floor effects were observed if $\geq 20\%$ of the participants had the highest and lowest scores, respectively (Holmes and Shea, 1997).

3. Results

Eighty patients were assessed by the PSP and the CGI-S after admission to the acute wards and before discharge from the hospital. The mean scores of the global score were 38.4 and 58.1 in the two assessments, respectively. The mean scores of the 4 domains in the PSP were 2.6-4.2 and 1.1-3.4 for the admission assessment and discharge assessment, respectively (Table 2). The severity of psychiatric illness of the participants was markedly ill at admission and mildly to moderately ill before discharge.

3.1. Internal responsiveness

Table 2 shows the results of internal responsiveness of the PSP. The values of the standardized effect size and the standardized response mean in the global score were 1.74 and 1.72, respectively. The standardized effect sizes and the standardized response means of the domains in the PSP were > 0.80, except for the self-care domain (0.68-0.74). The results of the paired t-tests showed that the score changes of the global score and the 4 domains were all statistically significant (p<0.001).

3.2. External responsiveness

Table 2 displays the correlations of the changes in scores of the PSP and those of the CGI-S. Good correlation (r=0.74) was shown between the changes in scores of the global score and those of the CGI-S. Moderate correlations (r=0.35-0.55) were found between the changes in scores of four domains and those of the CGI-S.

3.3. Score distribution

Obvious floor effect was found in the "disturbing and aggressive behaviors" domain on both assessments (admission: 21.3%; discharge: 87.5%). A negligible floor effect (1.3%) on the discharge assessment was observed in the self-care domain. Negligible ceiling effects (1.3%) on the admission assessment were noticed in two domains (i.e., "socially useful activities" and "personal and social relationships").

4. Discussion

To the best of our knowledge, this study is the first study to examine both internal and external responsiveness for inpatients with schizophrenia in a comprehensive manner. Our results revealed that the PSP had substantial internal responsiveness and sufficient external responsiveness. Changes in social functioning due to symptomatic remission or recovery can be detected by the PSP. The findings of this study are critical for clinicians and researchers

using the PSP to evaluate changes of social functioning.

We used two types of effect size (standardized effect size and standardized response mean) and paired t-test to examine internal responsiveness in this study. We found large values of the standardized effect size and the standardized response mean of the global score and moderate to large standardized effect sizes and standardized response means of the domains in the PSP. The paired t-test results showed that the score changes of the global score and each domain were statistically significant in inpatients with schizophrenia, which was similar to a previous study in outpatients with schizophrenia (Garcia-Portilla et al., 2011). Our findings demonstrate that the PSP had substantial internal responsiveness for inpatients with schizophrenia in the acute phase. The self-care domain showed lower values of two indices of effect size (less improvement), compared to the other domains. A possible reason is that nurses or other clinicians may do parts of the self-care tasks for their patients in the acute wards and consequently patients had little chance to perform or practice these self-care tasks. As these results in internal responsiveness (i.e., moderate to large values of ES and SRM) show, the PSP appears useful to assess recovery of social functioning for patients with schizophrenia.

Regarding external responsiveness, the results revealed good correlation between the changes in PSP global score and changes in CGI-S score and moderate correlations among the changes in scores of each domain in the PSP with those of the CGI-S. That is,

improvement exhibited in the global score and the 4 domains of the PSP reflected sufficient changes in clinical symptoms as measured by the CGI-S. Thus, the PSP appears able to detect changes, which are clinically important (i.e., changes in clinical symptoms). Our results support the external responsiveness of the PSP. Therefore, the PSP can be chosen as an outcome measure for interventions of social functioning in inpatients with schizophrenia.

An outcome measure should be responsive to change in order to demonstrate intervention efficacy. Floor and ceiling effects restrict a measure's ability to detect changes in individuals who score the lowest and highest scores, respectively (Fitzpatrick et al., 1998). An obvious floor effect was observed in the "disturbing and aggressive behaviors" domain at admission and at discharge. The responsiveness for the "disturbing and aggressive behaviors" domain may be underestimated. A possible reason for the floor effects of this domain may be due to the sample recruited. In this study, 21.3% and 87.5% of the patients displayed no verbal threats or physical assaults at admission and at discharge, respectively. Patients who displayed verbal threats or physical assaults may not be willing to participate in this study at admission. Thus, in this study, we may have recruited patients who displayed relatively no or less verbal threats or physical assaults. After receiving treatment, patients cooperated and were allowed to be discharged, resulting in a larger percentage of patients showing no verbal threats or physical assaults. Future studies recruiting patients with diverse severities of schizophrenia are needed to further validate the floor effect and responsiveness in the

"disturbing and aggressive behaviors" domain. For the other domains and the global score of the PSP, no to negligible floor or ceiling effects were found at admission and at discharge.

Generally, the PSP could discriminate between the participants with high and low levels of social functioning.

Four limitations should be considered in this study. First, we used a convenience sample (i.e., inpatients with schizophrenia in the acute phase) to examine two aspects of responsiveness of the PSP, which may have limited the generalization of our findings. Inpatients could not go back to their usual social role, maintain the same social relationships, and carry out self-care, which may cause bias. Moreover, there is no healthy control group in this study, which limits the comparison of results of responsiveness between patients with schizophrenia and healthy controls. Further studies with patients in different phases and including a healthy control group are needed to cross-validate our results. Second, we only used the CGI-S for examining the external responsiveness of the PSP. Further studies may use the other measures assessing symptom severity (e.g., the Positive and Negative Syndrome Scale) to examine the external responsiveness of the PSP. Third, we did not conduct analyses according to the item response theory (IRT) framework, because of the small sample size in this study. Additional studies conducting IRT analysis are warranted. Fourth, the same rater administered the PSP and the CGI-S after admission and before discharge from the hospital, which may contribute to the increase in the convergence of measurements. Future studies

with different raters administering the measures are needed to examine the responsiveness of the PSP.

In conclusion, the results of this study provide evidence that the PSP had sufficient responsiveness in inpatients with schizophrenia receiving treatments. Our results demonstrate that the global score and the four domains of the PSP can be useful for detecting actual changes of overall social functioning and each specific domain function over time for inpatients with schizophrenia.

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Table 1 Characteristics of the patients with schizophrenia (n = 80).

Characteristic	(50).
Gender, n (%)	
Male	40 (50.0)
Female	40 (50.0)
Age, mean year (SD)	43.1 (10.5)
Onset age, mean year (SD)	25.2 (8.4)
Number of admissions, mean (SD)	6.7 (6.1)
Education, n (%)	
Junior high school and below	12 (15.0)
Senior high school	30 (37.5)
College and above	38 (47.5)
Hollingshead Socioeconomic Status, n (%)	
Class III	2 (2.5)
Class IV	41 (51.3)
Class V	37 (46.3)
Schizophrenia subtype, n (%)	
Simple type	10 (12.5)
Disorganized	1 (1.3)
Paranoid type	17 (21.3)
Borderline type	1 (1.3)
Residual type	1 (1.3)
Schizoaffective disorder	1 (1.3)
Undifferentiated type	49 (61.3)
Type of antipsychotics, n (%)	
First generation	22 (27.5)
Second generation	66 (82.5)
Taking two types of antipsychotics	8(10.0)
CGI-S, mean (SD)	

	ACCEPTED MANUSCRIPT
Admission	5.0 (0.9)
Discharge	3.5 (0.6)
CGI-S score change, n (%)	a
No change	6 (7.8)
1-point	39 (50.6)
2-point	23 (29.9)
3-point	8 (10.4)
4-point	1 (1.3)

Note: SD = standard deviation; CGI-S = Clinical Global Impression-Severity scale.

^aThree patients' data were missing.



Table 2

Responsiveness indices of the PSP.

	Τ	RH		NU	MA	TEL	CEF	AC		C
			Global score	Domain ^a	Socially useful activities	Personal and social	relationships	Self-care	Disturbing and aggressive	behaviors
			38.4 ± 11.3		4.2 ± 0.6	3.9 ± 0.8		3.5 ± 0.8	2.6 ± 1.2	
	S		58.1 ± 8.1		3.4 ± 0.5	3.1 ± 0.5		3.0 ± 0.6	1.1 ± 0.4	
Standardized	office the same of		1.74	3	1.39	1.03		0.74	1.24	
Standardized			1.72		1.14	0.99	X.C	0.68	1.26	
Daired t-test		4	15.4 (<0.001)		10.2 (<0.001)	8.8 (<0.001)		6.1 (<0.001)	11.3 (<0.001)	
Change in CGI-S (r)			0.74		0.42	0.39		0.35	0.55	

Note: PSP = Personal and Social Performance scale; SD = standard deviation; CGI-S = Clinical Global Impression-Severity scale.

^aA lower domain score demonstrates better specific domain function. A lower global score represents worse overall social functioning.

^bCorrelations among changes in scores of the PSP and those of the CGI-S.

Highlights

- The Personal and Social Performance scale (PSP) is commonly used to assess social functioning with a global score and 4-domain scores in patients with schizophrenia
- The PSP had substantial internal responsiveness and sufficient external responsiveness in inpatients with schizophrenia receiving treatments.
- Changes in social functioning due to symptomatic remission or recovery can be detected by the PSP.