

The Portuguese version of the Clinical Global Impression – Schizophrenia Scale: validation study

Versão em português da Impressão Clínica Global - Escala de Esquizofrenia: estudo de validação

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Abstract

Objectives: The Clinical Global Impression – Schizophrenia Scale was designed to assess severity and treatment response in subjects with schizophrenia involved in naturalistic studies and daily clinical practice. The objective of this study is to validate the Portuguese version of the Clinical Global Impression – Schizophrenia Scale in Brazil by assessing its psychometric properties. **Method:** Cross-sectional validation study of the Portuguese version of the Clinical Global Impression – Schizophrenia Scale, tested in outpatients and inpatients with schizophrenia (DSM-IV, ICD-10) from 6 centers in Brazil. Concurrent validity and sensitivity to change were assessed by comparison with the Positive and Negative Syndrome Scale, which is considered the gold standard tool to evaluate patients with schizophrenia. Interrater reliability was evaluated by intraclass correlation coefficients (ICC) calculated based on the scoring of two concomitant raters. **Results:** 70 inpatients and 70 outpatients were evaluated. Total Clinical Global Impression – Schizophrenia Scale and Positive and Negative Syndrome Scale scores were highly correlated ($r = 0.79$; $p < 0.01$). Positive ($r = 0.86$), negative ($r = 0.79$), depressive ($r = 0.66$) and cognitive ($r = 0.75$) symptoms subscale scores were also correlated between both scales ($p < 0.01$). Sensitivity to change was significantly correlated between the Clinical Global Impression – Schizophrenia Scale and Positive and Negative Syndrome Scale ($r = 0.73$; $p < 0.01$). Interrater reliability was substantial for positive symptoms and total scores of the Clinical Global Impression – Schizophrenia Scale (ICC = 0.81 and 0.73), and moderate for negative, depressive, and cognitive symptoms score (0.64, 0.67 and 0.63, respectively). **Conclusions:** The Brazilian version of the Clinical Global Impression – Schizophrenia Scale is a valid and reliable instrument for the assessment of severity and treatment response in schizophrenic inpatient and outpatients.

Descriptors: Schizophrenia; Psychiatric status rating scales; Validity of tests; Validation studies; Multicenter study

Resumo

Objetivos: A Escala de Impressão Clínica Global – Esquizofrenia é um instrumento de aplicação simples e rápido, utilizado para avaliar a severidade de sintomas em pacientes com esquizofrenia. Pode ser aplicado em estudos naturalísticos e na prática clínica. O objetivo deste trabalho é estudar as propriedades psicométricas e validar a versão Brasileira da Escala de Impressão Clínica Global – Esquizofrenia em nosso meio. **Método:** Estudo transversal de validação da Escala de Impressão Clínica Global – Esquizofrenia, na versão em Português, em pacientes com esquizofrenia, hospitalizados e em tratamento ambulatorial (DSM-IV, ICD-10), selecionados em seis centros no Brasil. Validade concorrente e sensibilidade à mudança foram determinadas em comparação com a escala Positive and Negative Syndrome Scale, considerada padrão-ouro. Confiabilidade interavaliador foi determinada através de coeficientes de correlação intraclassa (ICC), calculados a partir das pontuações de dois avaliadores concomitantemente. **Resultados:** Setenta pacientes hospitalizados e 70 em tratamento ambulatorial foram incluídos. Os coeficientes de correlação de Pearson entre Escala de Impressão Clínica Global – Esquizofrenia e Positive and Negative Syndrome Scale foram: pontuação total (0,79), sintomas positivos ($r = 0,86$), negativos ($r = 0,79$), depressivos ($r = 0,66$) e cognitivos ($r = 0,75$, todos com $p < 0,01$). A confiabilidade interavaliadores da Escala de Impressão Clínica Global – Esquizofrenia foi alta para sintomas positivos e pontuação total; e moderada para sintomas negativos, depressivos e cognitivos. A sensibilidade ao grau de mudança foi moderadamente e significativamente correlacionada entre as duas escalas ($r = 0,73$, $p < 0,01$). **Conclusões:** A Escala de Impressão Clínica Global – Esquizofrenia em Português é um instrumento de boa validade e confiabilidade na avaliação da evolução de pacientes com esquizofrenia no Brasil, tanto em tratamento ambulatorial como hospitalizados.

Descritores: Esquizofrenia; Escalas de Graduação psiquiátrica; Validade dos testes; Estudos de validação; Estudo multicêntrico

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Introduction

The quantification of schizophrenia psychopathology requires multidimensional instruments capable of assessing its main clinical features, not only positive and negative symptoms,¹ but also other important dimensions commonly present in these patients.² Three instruments translated and validated for use in Brazilian populations of schizophrenic patients, the Positive and Negative Syndrome Scale (PANSS),^{3,4} the Brief Psychiatric Rating Scale (BPRS),^{5,6} and the Calgary Depression Rating Scale for Schizophrenia (CDRS)⁷ were developed for research purposes; being extensive and time-consuming (typically more than 30 min).

The Clinical Global Impression scale (CGI) is a concise instrument that has been used in studies of treatment response in schizophrenia, but it lacks specificity on psychosis and schizophrenia. In order to fill this gap, Haro et al. created the Clinical Global Impression - Schizophrenia Scale (CGI-SCH),⁸ a brief instrument adapted from the CGI scale⁹ and the CGI - Bipolar Version (CGI-BP) scale.¹⁰ The CGI-SCH was developed for use in the Schizophrenia Outpatient Health Outcomes (SOHO) Study,¹¹ an observational study of the outcomes of antipsychotic treatment in schizophrenia.

The CGI-SCH has two categories: severity of illness (CGI-SCH SI) and degree of change (CGI-SCH DC). The severity of illness evaluates the clinical situation during the week previous to the assessment, while the degree of change category evaluates the change of the severity of the disorder between two time-points. Each category contains five different ratings that evaluate positive, negative, depressive, cognitive and global symptoms, and a seven-point ordinal scale is applied to evaluate these categories. A short definition of each symptom's group is included in the instrument. Ratings of the CGI-SCH are related to the PANSS dimensions, but the term "SCH cognitive symptoms" is used instead of "SCH cognitive/disorganization".

Many psychiatrists face problems when using rating scales that are not translated and validated into Portuguese, particularly in clinical practice contexts. Thus, it would be very important to offer a simple, easy to administer, and accurate scale to evaluate patients with schizophrenia in Brazil. In the present study, a Portuguese version of the CGI-SCH was developed and validated for use in Brazilian schizophrenic patients. Its concurrent validity, interrater reliability and sensitivity to change were analyzed.

Method

This is an observational, longitudinal, naturalistic, multi-centric study for patients with schizophrenia. The original CGI-SCH English version was translated to Brazilian Portuguese using standard translation/back translation procedures after discussion with an expert panel (Appendix 1).

Individuals with diagnosis of schizophrenia, according to DSM-IV criteria, receiving psychiatric treatment either as inpatients or outpatients, both genders, and who were at least 18 years old were included in this study. Consecutive patients meeting inclusion criteria by clinical interview in each site were included in the study. Those subjects who refused to participate in the study were excluded. For inpatients, the first evaluation should be performed within 7 days after admission. All participants provided a written authorization to release information. Interviewers were trained in the use of the PANSS by a certified trainer.

Outpatients were evaluated in only one occasion by two psychiatrists. One of the psychiatrists conducted the interview and completed the three instruments (socio-demographic and clinical questionnaire, the CGI-SCH SI, and the PANSS) independently.

For inpatients, the first evaluation was similar to the outpatients' one. The second evaluation was done exclusively by one psychiatrist at discharge (or at 30 days from admission), and included the same instruments, except that CGI-SCH severity of illness and degree of change were rated. The order of administration, considering the complexity of scales, was the following: socio-demographic and clinical questionnaire, CGI-SCH, and PANSS.

For CGI-SCH analysis, concurrent validity was assessed by analyzing the agreement between CGI-SCH and PANSS ratings. Pearson correlation coefficients were used for statistical association, and considered significant when $p < 0.05$.

Interrater reliability was assessed by comparing the ratings of each of the CGI-SCH dimensions administered by two psychiatrists to the same patient, and analyzed using intraclass correlation coefficients (ICC).¹² ICC values range from 0 to 1, values of 0.7 and over indicate 'substantial agreement' and values of 0.5-0.7 indicate 'moderate agreement'.¹³

Sensitivity to change was evaluated by comparing the changes in the domains of the CGI-SCH (severity of illness and degree of change) and the PANSS from admission to discharge or 30 days after the first evaluation. Pearson correlation coefficients were calculated based on scores of both scales

Results

One hundred and forty patients were included in the study, 70 inpatients and 70 outpatients. The second evaluation was not carried out for 4 subjects (5.7%) because of loss of follow-up. Centers were from two States of the country (Minas Gerais and Rio Grande do Sul): Casa de Saúde Santa Maria (29.3% of included subjects), Instituto de Previdência dos Servidores do Estado de Minas Gerais (23.6%), Hospital Espírita de Porto Alegre (16.4%), Ambulatório da Faculdade de Medicina da Universidade Federal de Pelotas (10%), and Hospital Psiquiátrico São Pedro in Porto Alegre (8.6%). Most of patients were males (62%), unemployed (47.9%), with a mean PANSS total score of 81.2 (SD 25.2) in the first evaluation.

Comorbidity with drug and alcohol abuse/dependence affected 7.1% and 5.7% of the sample, respectively. For inpatients, mean length of hospital stay was 23.5 days (SD 8.2), and only 42.9% were still in hospital for the second evaluation. The most prescribed drugs during hospitalization included antipsychotics (92.9%), anxiolytics/sedatives (51.4%), anticholinergics (45.7%), and mood stabilizers (32.9%).

Intraclass correlation coefficients (ICC) were statistically significant for each domain of the instruments. For the CGI-SCH, substantial agreement was found for positive symptoms (0.81) and total score (0.73). For negative (0.64), depressive (0.67), and cognitive symptoms (0.63), interrater reliability was moderate. For the PANSS, interrater reliability was substantial for all domains, ranging from 0.77 to 0.89.

Regarding correlation between scales, it was moderate for positive, negative, cognitive and total score domains (0.86, 0.79, 0.75 and 0.79, respectively) and low for the depressive domain (0.66). All correlations were statistically significant, as presented in Table 1. For this analysis, every administration of the scales were considered, so the sample is not the number of patients but the number of administrations ($n = 342$).

Sensitivity to change was evaluated by comparing the change in scores of the CGI-SCH SI and PANSS. CGI-SCH SI scores decreased from 4.29 (SD 1.19) in visit 1 to 3.20 (1.28) in visit 2, while PANSS scores changed from 81.25 (SD 25.28) to 64.03 (23.45). CGI-SCH sensitivity to change

Table 1 - Pearson correlation between the CGI-SCH SI and PANSS (n = 342)

	CGI-SCH SI positive symptoms	CGI-SCH SI negative symptoms	CGI-SCH SI depressive symptoms	CGI-SCH SI cognitive symptoms	CGI-SCH SI total score
PANSS positive symptoms	0.86*	0.38*	0.18*	0.42*	0.69*
PANSS negative symptoms	0.32*	0.80*	0.26*	0.54*	0.57*
PANSS depressive symptoms	0.28*	0.15*	0.66*	0.01	0.22*
PANSS cognitive symptoms	0.51*	0.53*	0.01	0.75*	0.64*
PANSS Total score	0.72*	0.69*	0.27*	0.64*	0.79*

*p < 0.001

was also evaluated applying Pearson correlation coefficient on the change in scores of the CGI-SCH SI and PANSS, being moderate on positive, negative and total scores (0.79, 0.78 and 0.72, respectively), and modest for depressive and cognitive domains (0.55 and 0.64). All correlations were statistically significant. A subanalysis comparing interviewers and visits was consistent with the analysis including all evaluations in the same sample ($p < 0.01$ in all groups).

CGI-SCH degree of change was also compared to CGI-SCH SI and PANSS scores at discharge. These comparisons indicated a poor sensitivity of the instrument, with low correlation rates as measured by Pearson coefficients: from 0.5 (negative symptoms) to 0.7 (positive symptoms) in comparison to the CGI-SCH SI, and from 0.4 (depressive symptoms) to 0.6 (positive symptoms) in comparison to the PANSS.

Discussion

The CGI-SCH scale is a short instrument for evaluation of the distinct domains of schizophrenia, easy to administer and not time-consuming (1-2 minutes to fill in), which can be used either in clinical or research settings. No specific training is essential for its administration because the items to be addressed are simple and the ranking of patients' symptoms is based on clinical judgment. This could be a limitation between different evaluators with distinct clinical experience, but in this study, with psychiatrists from different backgrounds and settings, interrater reliability was substantial for total score and positive symptoms domain. In the negative and cognitive domains of the scale, where symptoms may be less specific, this is even more critical. Application of the CGI-SCH by professionals other than psychiatrists is possibly limited, and should not be considered for individuals without clinical psychiatric experience.

Overall, the psychometric properties of the CGI-SCH were good in this study, with a high concurrent validity and an accurate sensitivity to change, in comparison to PANSS scores. When compared to the study of development and validation of the CGI-SCH, by Haro et al.,⁹ the accuracy of the Brazilian version was very similar. Total score of the CGI-SCH SI Brazilian version had a higher concurrent validity, with correlation coefficients of 0.75 for the original version and 0.79 for the Brazilian. Sensitivity to change was also comparable between the Brazilian and the original versions of the CGI-SCH. Similarly to the original version of the CGI-SCH in English, the degree of change subscale has a poorer sensitivity to change in comparison to the CGI-SCH SI, which should be, for this reason, preferred to evaluate response to treatment and evolution of the disease.

This study suggests that the CGI-SCH is a simple and practical instrument that may be applied in Brazil, with similar properties to more complex and time-consuming scales such as the PANSS.

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Appendix 1 - CGI-SCH Severity of Illness Portuguese version

Gravidade da doença

Considerando toda sua experiência clínica com pacientes esquizofrênicos, qual a gravidade da doença do paciente durante a última semana?

	Normal, não doente	Minimamente doente	Levemente doente	Moderadamente doente	Marcadamente doente	Gravemente doente	Entre os doentes mais graves
Sintomas positivos (ex. alucinações, delírios ou comportamento bizarro)	1	2	3	4	5	6	7
Sintomas negativos (ex. embotamento afetivo, avolia e anedonia)	1	2	3	4	5	6	7
Sintomas depressivos (ex. tristeza, humor deprimido ou desesperança)	1	2	3	4	5	6	7
Sintomas cognitivos (ex. prejuízo da atenção, concentração ou memória)	1	2	3	4	5	6	7
Gravidade total	1	2	3	4	5	6	7