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The Clinical Global Impression— Schizophrenia scale: a simple instrument to measure the diversity of symptoms present in schizophrenia

Haro JM, Kamath SA, Ochoa S, Novick D, Rele K, Fargas A, Rodríguez MJ, Rele R, Orta J, Kharbeng A, Araya S, Gervin M, Alonso J, Mavreas V, Lavrentzou E, Liontos N, Gregor K, Jones PB on behalf of the SOHO Study Group. The Clinical Global Impression— Schizophrenia scale: a simple instrument to measure the diversity of symptoms present in schizophrenia.

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Objective: To describe the development and validation of the Clinical Global Impression–Schizophrenia (CGI-SCH) scale, designed to assess positive, negative, depressive and cognitive symptoms in schizophrenia.

Method: The CGI-SCH scale was adapted from the CGI scale. Concurrent validity and sensitivity to change were assessed by comparison with the Positive and Negative Symptom Severity (PANSS) and Global Assessment of Functioning (GAF) scales. To evaluate inter-rater reliability, all patients were assessed by two clinicians.

Results: Symptoms were assessed in 114 patients. Correlation coefficients between the CGI-SCH and the GAF and PANSS scores were high (most above 0.75), and were highest for positive and negative symptoms. Reliability was substantial (intraclass correlation coefficient, ICC > 0.70) in all but one dimension (depressive dimension, ICC = 0.64).

Conclusion: The CGI-SCH scale is a valid, reliable instrument to evaluate severity and treatment response in schizophrenia. Given its simplicity, brevity and clinical face validity, the scale is appropriate for use in observational studies and routine clinical practice.

J. M. Haro¹, S. A. Kamath², S. Ochoa¹, D. Novick³, K. Rele², A. Fargas¹, M. J. Rodríguez¹, R. Rele², J. Orta¹, A. Kharbeng², S. Araya¹, M. Gervin², J. Alonso, V. Mavreas⁴, E. Lavrentzou⁴, N. Liontos⁴, K. Gregor³, P. B. Jones² on behalf of the SOHO Study Group*

¹Research and Development Unit, Sant Joan de Déu-SSM, Sant Boi, Barcelona, Spain, ²University of Cambridge, Cambridge, UK, ³European Health Outcomes Research, Eli Lilly and Company Limited, Windlesham, Surrey, UK and ⁴University of Ioannina, Greece

Key words: psychiatric status rating scales; psychometrics; questionnaires; schizophrenia; signs and symptoms

Josep Maria Haro, Research and Development Unit, Dr Antoni Pujades 42, E-08830-Sant Boi de L, Barcelona,

Tel: +34 93 6002682; Fax: +34 93 6520051; E-mail: 27652jha@comb.es

Introduction

Schizophrenia is a serious mental disorder characterized by a number of symptoms. In the past, the symptoms of schizophrenia were classified as

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'florid' or 'productive', and 'defect' or 'deficit', which correspond roughly to the more up-to-date terms of positive and negative symptoms. Depression and cognitive symptoms also accompany positive and negative symptoms as psychopathological manifestations of schizophrenia. Depressed mood is common in individuals who suffer from schizophrenia, often arising from the individual's appraisal of psychosis and its implications for his or her perceived social identity, position and 'group fit'. Post-psychotic depression is associated with an increased risk of suicide (1, 2). Cognitive symptoms

were defined by Kraepelin in his first descriptions of dementia praecox. Taken together, these symptoms affect several areas of functioning, such as attention, executive functioning and memory.

The Positive and Negative Symptom Severity (PANSS) scale (3) is the scale used most often when assessing treatment response or clinical severity in schizophrenia, and allows evaluation of the symptoms of this condition. Factor analysis studies performed with the PANSS on large populations of patients with schizophrenia have identified five components in the symptomatology: positive, negative and cognitive/disorganization symptoms and two other affective dimensions (4–6). The findings using the PANSS scale have been consistent in different populations of patients (4-6). The PANSS depressive scale has been shown to be a valid measure of depressive symptoms in schizophrenia when compared with the Hamilton Rating Scale for Depression (HAM-D) and the Calgary Depression Scale for Schizophrenia (7).

However, the PANSS (like most scales that assess clinical severity) has been developed for use in a research environment, and while suitable for assessing treatment response in clinical trials, is time-consuming to administer (typically taking 30– 45 min). Shorter, simpler and easier-to-administer scales are badly needed, particularly for use in studies of treatment effectiveness, where evaluation of treatment occurs in a real practice environment. In this situation rapid assessment is mandatory, as a longer assessment would alter the normal course of the care that is under evaluation. Ouick, simple instruments could also be used in routine clinical practice. There is a need therefore for a simple, quick and easy-to-administer scale that is suitable for use in observational studies and routine clinical practice.

The objective of this paper is to describe the development and validation of the Clinical Global Impression–Schizophrenia (CGI-SCH) scale, a brief assessment instrument adapted from the Clinical Global Impression (CGI) scale. The CGI-SCH scale is designed to assess the main symptom dimensions in schizophrenia.

Material and methods

Development of the CGI-SCH scale

The CGI-SCH scale was developed for use in the Schizophrenia Outpatient Heath Outcomes (SOHO) Study (8), an observational study of the outcomes of antipsychotic treatment in schizophrenia. In creating the CGI-SCH scale, the objective

was to produce a simple, easy-to-administer instrument that could be used in observational studies and routine clinical practice in schizophrenia. It was decided that the instrument should:

- include evaluation of positive, negative, depressive and cognitive symptoms;
- be easy to understand;
- be quick and easy to administer;
- be valid and reliable; and
- be sensitive to change.

The CGI-SCH scale was adapted from the CGI scale (9) and the CGI-Bipolar Patients (CGI-BP) scale (10). The CGI scale is a simple instrument that evaluates the overall severity of mental disorders. The complete CGI scale consists of three different global measures designed to rate the effectiveness of a particular treatment:

- (i) severity of the illness (assessment of the current severity of symptoms);
- (ii) global improvement (comparison of the patient's baseline condition to his or her current condition); and
- (iii) efficacy index (evaluation of the patient's improvement from baseline in relation to treatment side-effects).

The CGI has been used previously in efficacy and effectiveness studies in schizophrenia (11–13), and has been shown to be sensitive to change: changes recorded by the CGI correlate with changes observed with more complex scales (14, 15). Nevertheless, the CGI has been criticized for being inconsistent and unreliable (10, 16, 17). Specific criticism includes the fact that the scale has asymmetric scaling, lacks standard definitions of illness severity and change, the change measures are redundant and the assessment of side-effects mixed with the evaluation of treatment change can complicate evaluation and interpretation (10).

Spearing et al. modified the CGI scale to improve its applicability in bipolar disorder (10). The CGI-BP overcomes the shortcomings of the CGI by eliminating the efficacy index, better defining the items, changing the anchor points and differentiating the rating of different types of symptoms (mania, depression and overall bipolar illness). The CGI-BP scale includes three categories (severity of illness, change from preceding phase and change from the worst phase of illness) and the evaluation of significant side-effects. Each of the categories has a different rating for manic, depressive and global symptoms. The CGI-BP has been used in recently conducted treatment trials in bipolar disorder (18, 19).

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Table 1. The CGI-SCH scale

| | Normal, not ill | Minimally ill | Mildly ill | Moderately ill | Markedly ill | Severely ill | Among the most severely ill |
|--------------------------------|--------------------|------------------|---------------|-------------------|-----------------|-----------------|--------------------------------|
| I. Positive symptoms | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| (e.g. hallucinations, delusion | ons or bizarre bel | naviour) | | | | | |
| 2. Negative symptoms | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| (e.g. affective flattening, a | volition or anhed | onia) | | | | | |
| 3. Depressive symptoms | 1 | 2 | 3 | 4 | 5 | 67 | |
| (e.g. sadness, depressed n | nood or hopeless | ness) | | | | | |
| 1. Cognitive symptoms | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| (e.g. impaired attention, co | ncentration or m | iemory) | | | | | |
| 5. Overall severity | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

| | _ | | | |
|---|--------|----|------|-----|
| ш | Degree | nŧ | chai | ann |
| | | | | |

| Compared to the previous e | Varuation , now mit Very much | Much | Minimally | No | Minimally | Much | Very much | |
|-----------------------------|----------------------------------|----------|-----------|--------|-----------|-------|-----------|-----|
| | improved | improved | improved | change | worse | worse | worse | N/A |
| 1. Positive symptoms | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 9 |
| (e.g. hallucinations, delus | ions or bizarre beha | aviour) | | | | | | |
| 2. Negative symptoms | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 9 |
| (e.g. affective flattening, | avolition or anhedo | nia) | | | | | | |
| 3. Depressive symptoms | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 9 |
| (e.g. sadness, depressed | mood or hopelessn | ess) | | | | | | |
| 4. Cognitive symptoms | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 9 |
| (e.g. impaired attention, o | oncentration or me | emory) | | | | | | |
| 5. Overall severity | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 9 |

^{*}In treatment trials with several evaluation points, use 'Compared to the phase immediately preceding this treatment trial' instead of 'Compared to the previous evaluation'.

Based on the CGI and CGI-BP, the CGI-SCH was developed for use with patients with schizophrenia. The CGI-SCH is simpler than the CGI and the CGI-BP scales as it consists of only two categories; severity of illness and degree of change (Table 1). The severity of illness category evaluates the situation during the week previous to the assessment, while the degree of change category evaluates the change from the previous evaluation (or from the phase preceding the treatment trial). Each category contains five different ratings (positive, negative, depressive, cognitive and global) that are evaluated using a seven-point ordinal scale. To help understanding, a short definition of each symptom is included in the instrument, and the instruction manual contains a more detailed definition of each dimension. Compared with the CGI instrument, several important changes have been introduced. The scaling of ratings has been modified to achieve more consistent intervals and time domains have been clarified. For example, the CGI instrument asks for the state of the patient 'at this time', while the CGI-SCH asks for the state of the patient 'during the last week'. The CGI efficacy index rates the improvement due to pharmacological treatment and relates this to the presence of side effects. As this index combines two diverse constructs, it is difficult to rate and probably not particularly reliable. The efficacy index has been deleted from the CGI-SCH and it is suggested that the evaluation of side-effects should be undertaken with specific scales.

The meaning of each of the ratings of the CGI-SCH is similar to the PANSS dimensions (positive, negative, depressive and cognitive/disorganization). The term 'CGI-SCH cognitive symptoms' is used instead of 'CGI-SCH cognitive/disorganization', as cognitive symptoms is a term with which psychiatrists are more likely to be familiar and the scale was designed for use by psychiatrists working in clinical practice rather than a research environment.

A brief user manual was developed to accompany the CGI-SCH (available from the authors). Following development of the CGI-SCH scale and the user manual, a process of cognitive debriefing was undertaken to test if the instrument was understood as it was intended.

The CGI-SCH was developed in English. The original English version was converted to Spanish using standard translation—backtranslation procedures, including expert panels, cognitive debriefing and pilot testing.

Patients

The study was conducted in three centres: Sant Joan de Déu-Serveis de Salut Mental in Barcelona, Spain, the University of Cambridge in the UK and the University of Ioannina in Greece. The study sample was designed to include a broad representation of patients with schizophrenia, including in-patients and outpatients, as well as patients experiencing an acute episode and those in a stable condition. Patients were recruited from three acute in-patient units and three outpatient services. The heterogeneity of this patient sample reflects the expectation that the CGI-SCH will be used in both in-patient and outpatient settings. Patients with a diagnosis of schizophrenia (according to IDC-10 or DSM-IV criteria), receiving psychiatric treatment, aged 18 years or older, and who gave informed consent for participation were included. No exclusion criteria were applied.

Methods

The objectives of the evaluation were to determine the concurrent validity, inter-rater reliability and sensitivity to change of the CGI-SCH scale. A battery of instruments were administered to the patients, including a sociodemographic and clinical questionnaire, the CGI-SCH scales, the PANSS (3, 20) and the Global Assessment of Functioning Scale (GAF) (21, 22).

Out-patients included in the study were rated by two clinicians (one of whom was usually the treating psychiatrist) using the battery of instruments. One of the clinicians conducted the interview and both clinicians completed the four questionnaires independently. Only the severity of illness (and not the degree of change) part of the CGI-SCH was completed for outpatients, as there was no follow-up assessment. In-patients were evaluated twice. The first evaluation took place during the first days after admission (this evaluation was equivalent to the evaluation of outpatients), and the second evaluation was conducted at discharge by one of the clinicians. The second evaluation included the same instruments, except that both categories of the CGI-SCH scales (severity of illness and degree of change) were rated. The order of administration of the questionnaires was the same in all cases and was sociodemographic and clinical questionnaire, CGI-SCH, PANSS and GAF.

The study protocol was approved by the ethics committees of the participating institutions.

Statistical analysis

Concurrent validity (a type of construct validity) is the capacity of an instrument to agree with other constructs that coexist with the one assessed by the test. Concurrent validity of the CGI-SCH scale was assessed by analysing the agreement between the CGI-SCH ratings with the PANSS (positive, negative, depressive, cognitive/disorganization and global scores), and the GAF. The CGI-SCH severity of illness (CGI-SCH SI) score for positive symptoms was compared with the PANSS positive score, for example, and the CGI-SCH SI score for depressive symptoms was compared with the PANSS depressive score. Pearson correlation coefficients were used to analyse the association. The PANSS scores were calculated using the following items (4, 23):

- positive (delusions, hallucinatory behaviour, grandiosity, suspiciousness, unusual thought content, lack of judgment and insight);
- negative (blunted affect, emotional withdrawal, poor rapport, passive/apathetic social withdrawal, lack of spontaneity and flow of conversation, motor retardation, active social avoidance, disturbance of volition);
- depressive (anxiety, guilt feelings, depression);
 and
- cognitive/disorganization (poor attention, conceptual disorganization, difficulty in abstract thinking, disorientation).

Sensitivity to change was analysed by calculating the effect size of the change of the CGI-SCH, the PANSS and the GAF ratings from admission to discharge. The effect size was calculated by dividing the mean change in the scale by the standard deviation. Sensitivity to change of the CGI-SCH scale was also evaluated by comparing the change in the CGI-SCH scale with the change in the PANSS and the GAF scales. As with the validity assessment, each of the CGI-SCH ratings was compared to the rating in the other scales that measured the same construct. Pearson correlation coefficients were used to analyse this association.

CGI-SCH degree of change (CGI-SCH DC) ratings measure the change of the severity of the disorder between two time-points (e.g. from the initiation of treatment to the assessment of its effectiveness). The CGI-SCH DC ratings at discharge were compared to the change in the CGI-SCH SI ratings from admission to discharge. Pearson correlation coefficients were used to analyse the agreement.

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Inter-rater reliability was assessed by comparing the ratings of each of the CGI-SCH dimensions made by the two clinicians for the same patient, analysed using intraclass correlation coefficients (ICC) (24). ICC values range from 0 to 1; values of 0.7 and over are considered to indicate 'substantial agreement' and values of 0.5–0.7 are considered to indicate 'moderate agreement' (25). As the GAF scale can have up to 100 possible scores, inter-rater reliability was calculated by grouping the scores into 5-point intervals.

Results

A total of 114 patients were included in the study; 50 patients from Spain (24 in-patients and 26 out-patients), 34 from the United Kingdom (19 in-patients and 15 out-patients) and 30 from Greece (eight in-patients and 22 out-patients). The proportion of men was 66.7%, 82.8% and 69.7% for Spain, United Kingdom and Greece, respectively. Mean age was 38.7 years (SD 10.2), 37.0 years (SD 11.6) and 33.9 years (SD 10.6) for Spain, United Kingdom and Greece, respectively. Patient sociodemographic and clinical characteristics are outlined in Table 2.

Correlation coefficients for the ratings in the CGI-SCH SI scales and the PANSS, and GAF scores are shown in Table 3. Values in bold are correlations that compare the CGI-SCH SI scales with the corresponding assessment in the other instruments. CGI-SCH SI ratings for positive, negative, cognitive symptoms and overall severity showed substantial agreement with the PANSS positive, negative, cognitive/disorganization and

Table 2. Patient sociodemographic and clinical characteristics

| | Characteristic | | |
|--|----------------|--|--|
| Setting | | | |
| In-patient (%) | 44.7 | | |
| Outpatient (%) | 55.3 | | |
| Gender (% male) | 69.7 | | |
| Mean (SD) age (years) | 36.9 (10.8) | | |
| Mean (SD) age at first treatment contact (years) | 24.1 (6.6) | | |
| Housing | | | |
| Independent residence (%) | 31.3 | | |
| Residence as dependent family member (%) | 43.7 | | |
| Supervised residence (%) | 20.5 | | |
| Homeless (%) | 3.6 | | |
| Other (%) | 0.9 | | |
| Mean (SD) PANSS score | | | |
| Global | 70.5 (22.4) | | |
| Positive | 18.2 (7.7) | | |
| Negative | 20.0 (9.1) | | |
| Depressive | 6.3 (2.5) | | |
| Cognitive | 8.8 (4.1) | | |
| Mean (SD) GAF score | 44.2 (19.9) | | |
| Number of patients | 114 | | |

total scores, respectively (Pearson correlation coefficients ranging from 0.75 to 0.86). Moderate agreement was found between the CGI-SCH depressive score and the PANSS depressive dimension and the CGI-SCH global score and the GAF scale (Pearson correlation coefficients of 0.60 and 0.67, respectively). As symptom dimensions are not totally independent, correlations between the CGI-SCH SI scales and the other scales that assessed symptoms not directly related to the symptoms being evaluated in that CGI-SCH dimension were also present. However, as expected, the values of the Pearson correlation coefficients were low (values ranging from 0.02 to 0.37), except for the cognitive and negative dimensions, where correlation coefficients were around 0.5. Scales that assess global symptomatology or functioning (CGI-SCH global score, PANSS total and GAF) were correlated to symptom dimensions, as global symptoms include the individual dimensions.

Sensitivity to change was analysed by assessing the effect size of the change in ratings during admission (Table 4). The effect sizes for CGI-SCH SI positive and global scores were higher than for negative, depressive and cognitive symptoms, and similar to those for the PANSS positive, total and GAF scores. Hospital admission to in-patient units is usually caused by an increase in positive symptoms and its improvement is the main objective of treatment. The effect sizes of the PANSS depressive and cognitive/disorganization scores were higher than the CGI-SCH SI depressive and cognitive ratings.

The Pearson correlation coefficients of the change in CGI-SCH SI scores with the corresponding PANSS dimension and GAF score (CGI-SCH SI positive with PANSS positive score, CGI-SCH SI negative with PANSS negative score, etc.) ranged from 0.62 (P < 0.001) for depressive symptoms to 0.70 (P < 0.001) for positive symptoms (data not shown). The correlation coefficients between the change in CGI-SCH SI scores and the CGI-SCH degree of change scores ranged from 0.63 (depressive symptoms) to 0.75 (cognitive symptoms).

Inter-rater reliability was substantial for the CGI-SCH SI positive, negative, cognitive and global scores (ICC ranged from 0.73 to 0.82) and moderate for the depressive scores (ICC = 0.64) (Table 5). Inter-rater reliability was slightly higher for the PANSS and GAF instruments than for the CGI-SCH scores.

Discussion

The CGI-SCH scale is a brief assessment instrument designed to evaluate positive, negative,

Table 3. Concurrent validity: correlation coefficients for the CGI-SCH severity of illness scales and PANSS and GAF scores

| Scale | CGI-SCI positive | CGI-SCH negative | CGI-SCH depressive | CGI-SCH cognitive | CGI-SCH global | PANSS positive | PANSS negative | PANSS depressive | PANSS cognitive | PANSS total |
|-----------------------|---------------------|---------------------|-----------------------|--------------------------|--------------------------|-------------------|-------------------|---------------------|--------------------|--------------------|
| CGI-SCH SI negative | 0.27 ^c | | | | | | | | | |
| CGI-SCH SI depressive | 0.18 ^b | 0.14 ^a | | | | | | | | |
| CGI-SCH SI cognitive | 0.27 ^c | 0.51 ^c | 0.02 | | | | | | | |
| CGI-SCH SI global | 0.73 ^c | 0.61 ^c | 0.16 ^a | 0.49 ^c | | | | | | |
| PANSS positive | 0.86° | 0.30° | 0.02 | 0.34 ^c | 0.73 ^c | | | | | |
| PANSS negative | 0.25 ^c | 0.80 ° | 0.16 ^b | 0.52 ^c | 0.54 ^c | 0.34 ^c | | | | |
| PANSS depressive | 0.26 ^c | 0.04 | 0.61° | 0.02 | 0.22 ^c | 0.16 ^b | 0.10 | | | |
| PANSS cognitive | 0.37 ^c | 0.51 ^c | 0.05 | 0.78 ^c | 0.54 ^c | 0.47 ^c | 0.59^{c} | 0.15 ^a | | |
| PANSS total | 0.64 ^c | 0.61 ^c | 0.14 ^a | 0.62 ^c | 0.75 [℃] | 0.78 ^c | 0.75 ^c | 0.32 ^c | 0.797 ^c | |
| GAF | -0.55 ^c | -0.51 ^c | -0.108 | -0.51 ^c | -0.67 ^c | -0.60^{c} | -0.47^{c} | -0.13^{a} | -0.534^{c} | -0.66 ^c |

SI, severity of illness.

Table 4. Analysis of sensitivity to change: effect size of the change in CGI-SCH, PANSS and GAF scores from admission to discharge in in-patients

| Scale | Effect size |
|-----------------------|-------------|
| CGI-SCI SI positive | 0.81 |
| CGI-SCH SI negative | 0.14 |
| CGI-SCH SI depressive | 0.31 |
| CGI-SCH SI cognitive | 0.25 |
| CGI-SCH global | 0.79 |
| PANSS positive | 0.93 |
| PANSS negative | 0.24 |
| PANSS depressive | 0.49 |
| PANSS cognitive | 0.50 |
| PANSS total | 0.80 |
| GAF | 0.90 |

Table 5. Inter-rater reliability analysis: ICC of the evaluations of the two clinicians and the battery of instruments

| Scale | ICC |
|-----------------------|------|
| CGI-SCI SI positive | 0.82 |
| CGI-SCH SI negative | 0.73 |
| CGI-SCH SI depressive | 0.64 |
| CGI-SCH SI cognitive | 0.77 |
| CGI-SCH global | 0.75 |
| PANSS positive | 0.88 |
| PANSS negative | 0.77 |
| PANSS depressive | 0.80 |
| PANSS cognitive | 0.85 |
| PANSS total | 0.87 |
| GAF | 0.87 |

depressive, cognitive symptoms and overall severity in schizophrenia. The scale aims to translate clinical judgement into ratings that reflect the diversity of symptoms present in schizophrenia. The ratings are based on clinical judgement and the assessment is not time consuming to administer.

Overall, the psychometric properties of the CGI-SCH scale were good. CGI-SCH inter-rater reliability measured with the ICC was similar to the PANSS dimension score ICC in most ratings,

except for the depressive score (CGI-SCH depressive rating ICC was 0.64 compared with 0.80 in the PANSS depressive dimension). The association of the CGI-SCH scales with the PANSS dimension ratings measured with the Pearson correlation coefficient was high for all of the ratings, except, again, for the depressive symptoms (Pearson correlation coefficient of 0.6, indicating a moderate relationship).

The CGI-SCH global rating correlation with the PANSS total and GAF scores was apparently lower than that for the positive, negative and cognitive scores (Pearson correlation coefficients of 0.75 and 0.67 for the correlation with the PANSS total and GAF scores, respectively, compared with 0.86, 0.80 and 0.78, for the positive, negative and cognitive scores, respectively). However, it should be remembered that the PANSS global, GAF and CGI-SCH global rating do not measure the same constructs. The CGI-SCH global score assesses global severity of the disorder, including both symptoms and interference with functioning. The PANSS total score only evaluates symptoms and not interference, and the GAF scale is made up of two independent scales (severity of symptoms and interference) and the final rating is the lowest of both. The correlation between the GAF and PANSS total scores was 0.66.

Some correlation exists between the intensity of the symptoms in different dimensions. For example, the CGI-SCH negative symptoms score is related to the CGI-SCH cognitive score. Clinical sense dictates that patients with more negative symptoms are also likely to score higher in terms of cognitive symptoms. The correlation between depressive, positive and negative symptoms has also been found by other authors (26–28).

Sensitivity to change for the CGI-SCH scale was similar to sensitivity to change for the PANSS and GAF, except for the depressive dimension, where

 $^{{}^{}a}P < 0.05; {}^{b}P < 0.01; {}^{c}P < 0.001.$

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sensitivity to change was lower for the CGI-SCH depressive score.

When considering these findings, it should be remembered that the design of the study tried to mimic routine clinical practice. The rating of the CGI-SCH scale was recorded after an interview that lasted approximately the same time as a clinical visit. After the rating of the CGI-SCH scale, the interview was extended to administer the rest of the battery of tests and further questioning was done. This series of events and timing was designed to compare the information obtained from the CGI-SCH scale administered at the end of a short visit, with the information obtained during a typical evaluation with the PANSS and GAF scales. The training of psychiatrists in the use of the CGI-SCH scale was based only on the CGI-SCH instruction manual. Previous research has shown that training duration is associated with increased inter-rater reliability (29, 30), and it is probable that with additional training, correlation of the CGI-SCH with the PANSS and inter-rater reliability would be higher.

Conclusion

From these results, it can be concluded that the CGI-SCH scale is a valid and reliable instrument with which to evaluate severity and treatment response in schizophrenia. Support was stronger for the positive, negative, cognitive and global ratings than for the depressive ratings. The simplicity of the instrument and the fact that it is quick to administer make it appropriate for use in observational studies and routine clinical practice.

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