Original

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The Schizophrenia Quality of Life Scale Revision 4 (SQLS-R4) questionnaire. A validation study with Spanish schizophrenia spectrum outpatients

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Introduction. The Schizophrenia Quality of Life Scale Revision 4 (SQLS-R4) is a disease-specific subjective Quality of Life (QL) questionnaire for patients with schizophrenia. This study assesses the psychometric properties of the SQLS-R4 when applied to a sample of Spanish schizophrenia spectrum outpatients with stable disease.

Methods. The SQLS-R4 and EUROQOL-5D-5L were completed once by 168 schizophrenia and schizoaffective disorder patients. Of these, 61 also completed the WHOQOL-BREF and 50 completed the SQLS-R4 one week later. Psychometric evaluation of structure, reliability and validity was conducted.

Results. Multi-trait scaling confirmed the two multiitem scales. Internal consistency for the two scales (Cronbach's coefficients>0.89) and the whole questionnaire (0.96) was adequate, as was test-retest reliability (intraclass correlation coefficients>0.79). Correlations with related areas of EUROQOL-5D-5L and WHOQOL-BREF (Spearman's Rho>0.60) supported convergent validity. Divergent validity was confirmed through low correlations with less-related areas of these two questionnaires (Spearman's Rho<0.30). Patients with higher levels of depression, more acute episodes and schizoaffective disorder had higher QL limitations.

Conclusions. The SQLS-R4 is a reliable and valid instrument when applied to Spanish outpatients with stable dis-

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Keywords: Quality of Life, Spanish, Validation, Questionnaire, Schizophrenia

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El cuestionario Schizophrenia Quality of Life Scale Revision 4 (SQLS-R4). Estudio de validación con pacientes españoles ambulatorios del espectro de la esquizofrenia

Introducción. El cuestionario *Schizophrenia Quality of Life Scale Revision-4* (SQLS-R4) es una escala de Calidad de Vida (CV) subjetiva específica para pacientes con esquizofrenia. El presente estudio evalúa sus propiedades psicométricas en una muestra de pacientes ambulatorios españoles del espectro de la esquizofrenia con enfermedad estable.

Metodología. Los cuestionarios SQLS-R4 y EURO-QOL-5D-5L fueron completados una vez por 168 pacientes con esquizofrenia y trastorno esquizoafectivo. De ellos, 61 también contestaron el WHOQOL-BREF, y 50 el SQLS-R4 una semana después. Se ha realizado una evaluación psicométrica de su estructura, fiabilidad y validez.

Resultados. El análisis multirasgo-multimétodo confirma las dos escalas multi-items. La consistencia interna de las dos escalas (coeficiente de Cronbach>0,89) y del cuestionario global (0,96) y la fiabilidad test-retest (coeficiente de correlación intraclase>0,79) han sido adecuadas. Las correlaciones con áreas relacionadas del EUROQOL-5D-5L y del WHOQOL-BREF (Spearman-Rho>0,60) y con áreas menos relacionadas de estos dos cuestionarios (<0,30) apoyan la validez convergente y divergente. Pacientes con más ingresos hospitalarios, mayor nivel de depresión y con un diagnóstico de trastorno esquizoafectivo han presentado puntuaciones más altas de CV (mayores limitaciones).

Conclusiones. El cuestionario SQLS-R4 es un instrumento fiable y válido en su aplicación a pacientes ambulatorios españoles con enfermedad estable. Los resultados de nuestro estudio de validación coinciden con los de otros estudios psicométricos realizados en Europa y otras áreas culturales.

Palabras clave: Calidad de Vida, Español, Validación, Cuestionario, Esquizofrenia

INTRODUCTION

Quality of Life (QL) is considered a key aim of the interventions offered to patients with psychosis. Much emphasis is placed on developing strategies for maintaining and improving the QL of patients². Quality of Life (QL) has also become an important outcome measure of the various treatments in psychosis¹.

It is believed nowadays that patients should assess their QL (subjective assessment) through PRO (Patient Reported Outcomes) instruments^{3,4}. This assessment can be complemented with objective data (such as the patient's level of income), which can be recorded by a professional^{1, 5}.

QL in schizophrenia is understood to be a multidimensional concept^{3,6,7}. It can be assessed through generic QL questionnaires, which evaluate areas common to various diseases, and combined with disease-specific QL questionnaires, which assess dimensions that are more related to schizophrenia⁸⁻¹⁰.

Wilkinson et al.¹¹ developed the SQLS (Schizophrenia Quality of Life Scale), a widely used disease-specific subjective QL questionnaire for patients with schizophrenia. This questionnaire includes three dimensions: psychological, motivation and energy, and symptoms and side effects. Nowadays, a revised version of this instrument –the SQLS-R4 (Schizophrenia Quality of Life Scale Revision 4)– is available¹².

The SQLS-R4 is also a self-administered scale that measures QL from the patient's perspective. It has been increasingly used in different populations of patients with schizophrenia^{13,14}. The SQLS-R4 has shown high content validity. This may be because it was designed following discussions with patients¹⁵, which enabled items that are highly relevant to them to be included. Numerous psychometric studies of the SQLS-R4 questionnaire have been conducted in other European countries^{12,16} and other cultural areas¹⁷⁻²⁰.

QL studies performed in patients with psychosis from different cultural areas have shown some cross-cultural differences²¹. These differences could be related to sociodemographic factors, such as living conditions, but also to the criteria these patients have for assessing their QL.

A satisfactory validation study of the SQLS-R4 for Spain would demonstrate the availability of an instrument that can be used to adequately evaluate QL in Spanish schizophrenia spectrum outpatients. It would also be useful to compare the results of studies conducted in Spain with those from other countries. In Spain there is a lack of studies assessing the QL of schizophrenia spectrum outpatients.

The aims of this paper are to determine the psychometric properties of the SQLS-R4 questionnaire when applied to a sample of Spanish schizophrenia spectrum outpatients with stable disease and to compare these results with those of validation studies performed in Europe and other cultural areas.

METHODS

Participants

A consecutive sample of schizophrenia and schizoaffective disorder patients (F20 and F25 ICD-10 criteria) who received a multiprofesional intervention aimed at improving QL and other aspects were recruited between May 2014 and October 2016 at two institutions, i.e. a rehabilitation service (a community day center) and an outpatients' clinic.

All participants were adults (>18 years) with stable disease and mild or no positive symptoms (scores <2 in all SAPS (Scale for the Assessment of Positive Symptoms) items)²². They had spent at least three weeks in the service or had had over three consultations in the outpatients unit. Patients with organic mental disorders or whose cognitive level prevented them from completing the questionnaires were excluded.

Measures

All patients completed the subjective QL questionnaires SQLS-R4¹² and EUROQOL-5D-5L²³. The Schizophrenia Quality of Life Scale Revision 4 (SQLS-R4) is a specific QL scale for

people with schizophrenia. The SQLS-R4 comprises 33 items divided into two sub-scales (vitality and psychosocial feelings) and a global QL score. Scores in the two areas and in the global scale range from 0 to 100, with high values indicating low QL. This instrument has been translated into Spanish through a forward-backward translation process¹⁵.

The EUROQOL-5D-5L is a generic QL self-report questionnaire comprising five health dimensions (mobility, selfcare, usual activities, pain/discomfort and anxiety/depression) that can be combined to produce a societal preferential value of health status (EUROQOL value). Scores range from 0 to 1. It also includes a self-rated health status (EUROQOL health), a visual analogue scale whose scores range from 0 to 100. In both cases, a high score represents a high QL.

The first 61 patients also filled in the WHOQOL-BREF²⁴, which had previously been validated for use in Spain^{8,25}. The World Health Organization Quality of Life-Brief Form²⁴ is also a generic QL instrument that has been used in patients with schizophrenia^{8,25}. It comprises 30 items divided into four domains (physical, psychological, social relationship and environment) plus two general items (which were not included in our study). Scores for the four specific QL domains range from 0 to 100. High scores indicate good QL.

Other instruments

Schizophrenia symptomatology was assessed by the specific symptom rating scales SANS (Scale for the Assessment of Negative Symptoms) and SAPS (Scale for the Assessment of Positive Symptoms–inclusion criteria)²². SANS assesses five negative symptoms while SAPS assesses four positive symptoms. Global scores range from 0 to 30 in the SANS scale and from 0 to 20 in the SAPS scale. High scores indicate high levels of symptoms in both cases. Depression was measured with the Calgary Depression Scale for Schizophrenia²⁶, whose scores range from 0 to 27. High scores indicate a high depression level.

Data collection procedures

All patients who satisfied the inclusion criteria were addressed during one of their visits to their treating professionals. They were interviewed, given oral and written information about the study, and invited to participate. Patients who provided informed consent completed the EURO-QOL-5D-5L and the SQLS-R4, and the first group of 61 patients completed the WHOQOL-BREF. The last 50 patients from the Rehabilitation Unit completed the SQLS-R4 one week later. Other demographic data (gender, age, level of studies, cohabitance, employment status and economic income) were obtained from the patient, while other clinical data (time since diagnosis and number of acute episodes) were obtained from the clinical record. The study was approved by the Research Ethics Committee of the Health Department and conducted in accordance with the ethical standards of the Declaration of Helsinki.

Statistical analysis

We considered a sample size of 165 patients based on the recommendation of 5-10 cases per variable for psychometric studies²⁷. Clinical and demographic characteristics and QL scores were summarized using descriptive statistics for the whole sample and for the two diagnosis groups (schizophrenia and schizoaffective disorder). Comparisons between these groups were conducted using the Chi-square test or Mann-Whitney test.

Multitrait scaling analysis²⁸ was performed in the first assessment to examine whether the individual items of SQLS-R4 could be aggregated into hypothesized multi-item sub-scales. Evidence of item convergent validity was defined as an item-own-scale correlation of P>0.40 (corrected for overlap). Item discriminant validity was supported and a scaling success was counted when the correlation between an item and its hypothesized sub-scale (corrected for overlap) was higher than its correlation with the other sub-scale. Scaling failures were identified when an item correlated lower with its hypothesized sub-scale (corrected for overlap) than with the other sub-scale. The Internal consistency reliability of the scales was measured (Cronbach's alpha coefficient>0.70 criteria) in the first assessment²⁹. Test-retest reliability was studied through intraclass correlation coefficients (ICC) between the scores in the first and second assessments in the SQLS-R4 (ICC>0.60 for criteria).

Questionnaire validity was studied using two approaches. For convergent and divergent validity, correlations between the different areas of SQLS-R4 (two sub-scales and global score) and the EUROQOL-5D-5L, and between the SQLS-R4 areas and the four WHOQOL-BREF scales were calculated in the first measurement (Spearman's correlation coefficients; two-tail analysis, also in the multitrait analyses). Scales and items whose contents are conceptually related were expected to correlate substantially with each other (Spearman's Rho>0.60 large correlation), e.g. EURO-QOL-5D-5L anxiety/depression with vitality, psychosocial feelings and Global score; EUROQOL-5D-5L value and health with SQLS-R4 Global score; WHOQOL-BREF psychological domain with the two SQLS-R4 subscales and global score; WHOQOL-BREF physical domain with SQLS-R4 vitality scale. Conversely, areas with less in common were expected to correlate less (Spearman's Rho<0.30 small correlation): e.g. EU-ROQOL-5D-5L mobility and selfcare with the different SQLS-R4 areas; WHOQOL-BREF environment domain with vitality.

Known group comparison analysis was conducted in the first assessment to discriminate between subgroups of patients. Linear univariate regression models were fitted with the QL scores in the SQLS-R4 as response variables. Explanatory (independent) variables were: (1) sociodemographic variables: age, gender, employment status (1= unemployed; 2= other situation: student, on sick leave, pensioner, or working). Clinical variables were: time since diagnosis, number of acute episodes, diagnoses, negative symptoms (SANS), and depression (Calgary). These analyses were conducted for the whole sample as well as for patients with schizophrenia and schizoaffective disorders separately.

Greater QL was expected from patients who were younger³⁰, were not unemployed³¹, had less time since diagnosis², had a lower number of acute episodes¹⁸, were diagnosed with schizophrenia³², or had a lower level of negative

| Table 1 Sociode | mographic and clinical characteristics of t | he sample | | | |
|----------------------------|---|-----------|------------|-------|-------|
| | Characteristics | No. | Percentage | Mean | S.D. |
| Gender | Female | 80 | 47.6 | | |
| | Male | 88 | 52.4 | | |
| Present age | (range 18–74) | | | 39.6 | 11.5 |
| Level of study | Less than compulsory | 20 | 11.9 | | |
| | compulsory | 66 | 39.3 | | |
| | ≥compulsory & < university | 59 | 35.1 | | |
| | University | 23 | 11.7 | | |
| Cohabitance | Alone | 23 | 13.7 | | |
| | Partner | 15 | 8.9 | | |
| | Partner and children | 10 | 5.9 | | |
| | Family of origin | 100 | 59.6 | | |
| | Other | 20 | 11.9 | | |
| Employment status | Student | 5 | 3 | | |
| | Working | 5 | 3 | | |
| | Sick leave | 20 | 12.1 | | |
| | Unemployed | 70 | 41.7 | | |
| | Pensioner | 68 | 40.2 | | |
| Economic income | (range 80-2500) | | | 675.7 | 532.1 |
| Diagnosis | Schizophrenia | 105 | 62.8 | | |
| | Schizoaffective disorder | 63 | 37.2 | | |
| N of acute episodes | (Range 0–15) | | | 3.4 | 2.6 |
| Time since diagnoses (yrs) | (1-54) | | | 13.7 | 10.8 |
| SANS | (range 0-24) | | | 8.9 | 4.9 |
| Calgary | (range 0-21) | | | 6.1 | 5.1 |

symptoms^{8,33} and depression²⁰. No differences were expected between gender-based groups¹⁵.

RESULTS

Of the 176 patients that were addressed, 168 filled in the SQLS-R4 and the EUROQOL-5D-5L. Of these patients, 105 (62.8%) had been diagnosed with schizoaffective disorder. Reasons for not completing the questionnaires were administrative failure (5 cases) and patient refusal (3 cases).

All SQLS-R4 questionnaires had >90% items answered. Socio-demographic and clinical characteristics are shown in table 1. The mean age was 39.6. Patients at different levels of studies were represented in the sample. Also, 59.6 % lived with their family of origin and 3% were working (with a salary), while 41.7% were unemployed (considered candidates for a job, including at special work centres; some of them could be receiving unemployment benefit or state financial aid), and 40.2% were pensioners (who could no longer work and were receiving a pension). The mean number of acute episodes was 3.4. Patients with schizoaffective disorder were older (mean age: 37.6 vs. 42.5) and had a higher percentage of pensioners (32.5% vs. 53.9%), a lower percentage of unemployed patients (49.5% vs. 28.6%), and a higher mean number of acute episodes (2.7 vs. 4.4) than patients with schizophrenia (see Annex 1).

Questionnaire descriptive statistics

Table 2 shows that the mean scores were moderate in most QL areas: between 36.6 and 39.4 (QL limitations) in the SQLS-R4 (first assessment); between 49.2 and 62.7 in the WHOQOL BREF; 62.7 in the EUROQOL health; and 0.80 in the EUROQOL value. The percentage of respondents at floor in the first assessment in the SQLS-R4 questionnaire was low. There was no ceiling effect. There was no floor or ceiling effect in the retest assessment. The range of scores was broad in all the SQLS-R4 questionnaire areas in the two assessments (Table 2). Patients with schizoaffective disorder had a lower QL (more limitations) in the three areas of the

| Table 2 | Scores in | n the first a | nd test-re | test assess | sment | | | |
|---|---|--|--|--------------|---|----------------------|---|------------------------------|
| Area | | Mean | S.D. | Alpha | Floor (%) | Ceiling (%) | Range | ICC (p-value) |
| SQLS-R4 | | | | | | | | |
| Psycho-social | 1 st | 36.6 | 21.5 | 0.94 | 1.2 | No | 0- 93.7 | 0.81(<0.001) |
| | Retest* | 36.8 | 23.1 | | No | No | 2.5-85 | |
| Vitality | 1 st | 39.4 | 18.9 | 0.89 | 0.6 | No | 0 -80.8 | |
| | Retest* | 34.9 | 20.3 | | No | No | 1.9-75.0 | 0.79(<0.001) |
| Total | 1 st | 37.7 | 19.6 | 0.96 | 0.6 | No | 0-88.6 | |
| | Retest* | 35.7 | 21.6 | | No | No | 3.8-80.3 | 0.83(<0.001) |
| EUROQOL- 5D-5I | L | | | | | | | |
| EUROQOL value | | 0.79 | 0.21 | | | | | |
| EUROQOL health | | 62.7 | 21.8 | | | | | |
| WHOQOL-BREF* | | | | | | | | |
| Physical | | 56.2 | 15.6 | | | | | |
| Psychological | | 49.2 | 21.1 | | | | | |
| Social relationship | p | 51.9 | 20.2 | | | | | |
| Environment | | 62.7 | 15.7 | | | | | |
| Vitality Total EUROQOL- 5D-51 EUROQOL value EUROQOL health WHOQOL-BREF* Physical Psychological Social relationship Environment | Retest* 1 st Retest* 1 st Retest* L | 36.8 39.4 34.9 37.7 35.7 0.79 62.7 56.2 49.2 51.9 62.7 | 23.1 18.9 20.3 19.6 21.6 0.21 21.8 15.6 21.1 20.2 15.7 001-5D-51 at | 0.89 0.96 | NO 0.6 NO 0.6 NO BREE (*61 patie | No No No No | 2.5-85 0 -80.8 1.9-75.0 0-88.6 3.8-80.3 | 0.79(<0.001) 0.83(<0.001) |

1st Measurement: scores in the SQLS-R4, EUROQOL-5D-5L and WHOQOL-BREF (*61 patients) questionnaires in the first measurement Retest: scores in the SQLS-R4 in the retest measurement. ICC: Intraclass Correlation Coefficient SQLS-R4 as well as in the EUROQOL value and EUROQOL health areas of the EUROQOL-5D-5L than patients with schizophrenia (see Annex 1).

Multitrait scaling analysis

All items (except item 7; Rho=0.38) exceeded the 0.4 criterion for *convergent validity*. Item *discriminant validity* was successful in all analyses except for items 11, 26 and 33 (differences between the correlations item own sub-scale and the other sub-scale range from 0.03 to 0.06) (table 3).

Internal consistency reliability. The two subscales and the global scale fitted the >0.7 criterion (table 2). Test-retest analyses showed ICC coefficients between 0.79 and 0.83.

Convergent validity. The *highest correlations* between the SQLS-R4 and the EUROQOL-5D-5L (Spearman's Rho>0.60) were found between psychosocial feelings, vitality and SQLS-R4 global score, and EUROQOL-5D-5L anxiety/ depression (0.62 to 0.78); and between vitality and SQLS-R4 Global score, and EUROQOL-5D-5L value (-0.63 and -0.62 respectively). The *highest correlations* between the SQLS-R4 and the WHOQOL-BREF were found between psychosocial feelings, vitality and SQLS-R4 Global score, and WHO-QOL-BREF psychological domain (-0.65, -0.71 and -0.72 respectively); and between vitality and SQLS-R4 Global score, and WHOQOL-BREF physical domain (-0.62 and -0.61 respectively) (table 4).

Divergent validity. Conversely, weak correlations were found between the various SQLS-R4 areas and EURO-QOL-5D-5L mobility and selfcare (Spearman's Rho between 0.25 and 0.29); between SQLS-R4 psychosocial feelings and Global score, and EUROQOL-5D-5L pain (0.25 and 0.28 respectively); and between the SQLS-R4 vitality area and the WHOQOL-BREF social relationship domain (-0.28) (table 4).

Known group comparison. No significant relationships were found between age, gender, employment status, time since diagnosis, negative symptoms (SANS), and any of the QL areas. Depression, the number of acute episodes and diagnoses showed significant relationships with the QL areas studied. Patients with a higher level of depression, with more acute episodes and with schizoaffective disorder had lower QL scores (see table 5).

When the known groups comparisons were studied separately in each of the two diagnosis groups (schizophrenia and schizoaffective disorder), the main features were maintained in both groups but with slight differences between

| Table 3 | Multitrait | t analyses | | | | | | |
|---------|--------------------------|------------|--------------|--|--|--|--|--|
| | Psychosocial feelings | Vitality | Discriminant | | | | | |
| Ítem 3 | 0.53 | 0.39 | YES | | | | | |
| ltem 4 | 0.59 | 0.42 | YES | | | | | |
| ltem 5 | 0.80 | 0.66 | YES | | | | | |
| ltem 6 | 0.66 | 0.53 | YES | | | | | |
| Item 8 | 0.52 | 0.48 | YES | | | | | |
| Item 10 | 0.66 | 0.63 | YES | | | | | |
| Item 11 | 0.64 | 0.67 | NO | | | | | |
| Item 13 | 0.74 | 0.61 | YES | | | | | |
| Item 15 | 0.70 | 0.61 | YES | | | | | |
| Item 16 | 0.70 | 0.59 | YES | | | | | |
| ltem 17 | 0.59 | 0.44 | YES | | | | | |
| ltem 18 | 0.57 | 0.48 | YES | | | | | |
| ltem 19 | 0.65 | 0.54 | YES | | | | | |
| ltem 21 | 0.73 | 0.62 | YES | | | | | |
| ltem 22 | 0.67 | 0.65 | YES | | | | | |
| Item 24 | 0.79 | 0.65 | YES | | | | | |
| Item 25 | 0.53 | 0.45 | YES | | | | | |
| ltem 27 | 0.81 | 0.79 | YES | | | | | |
| ltem 29 | 0.60 | 0.54 | YES | | | | | |
| ltem 30 | 0.65 | 0.46 | YES | | | | | |
| ltem 1 | 0.54 | 0.68 | YES | | | | | |
| Item 2 | 0.53 | 0.62 | YES | | | | | |
| ltem 7 | 0.28 | 0.38 | YES | | | | | |
| Item 9 | 0.56 | 0.59 | YES | | | | | |
| ltem 12 | 0.38 | 0.46 | YES | | | | | |
| Item 14 | 0.40 | 0.41 | YES | | | | | |
| ltem 20 | 0.44 | 0.45 | YES | | | | | |
| Item 23 | 0.71 | 0.72 | YES | | | | | |
| Item 26 | 0.63 | 0.57 | NO | | | | | |
| ltem 28 | 0.41 | 0.50 | YES | | | | | |
| Item 31 | 0.50 | 0.59 | YES | | | | | |
| Item 32 | 0.57 | 0.67 | YES | | | | | |
| Item 33 | 0.68 | 0.63 | NO | | | | | |

Cells in grey: correlations between each item and its own scale (corrected for overlap)

Cells in white: correlations between each item and the other scale Numbers underlined and in bold: highest correlations between an item and the various scales Table 4

Convergent and divergent validity

| | | | | SQLS-R4 | | |
|---------------------|---------------|---------|-------|---------|-------|---------|
| | Psycho-social | | Vi | tality | G | lobal |
| | Rho* | P value | Rho* | P value | Rho* | P value |
| EUROQOL- 5D-5L | | | | | | |
| Mobility | 0.27 | 0.001 | 0.25 | 0.001 | 0.27 | 0.001 |
| Self-care | 0.26 | 0.001 | 0.28 | <0.001 | 0.29 | <0.001 |
| Usual activities | 0.43 | <0.001 | 0.48 | <0.001 | 0.49 | <0.001 |
| Pain/discomfort | 0.25 | 0.001 | 0.30 | <0.001 | 0.28 | <0.001 |
| Anxiety/depression | 0.67 | <0.001 | 0.62 | <0.001 | 0.78 | <0.001 |
| EUROQOL value | -0.57 | <0.001 | -0.63 | <0.001 | -0.62 | <0.001 |
| EUROQOL health | -0.57 | <0.001 | -0.59 | <0.001 | -0.60 | <0.001 |
| WHOQOL-BREF | | | | | | |
| Physical | -0.52 | <0.001 | -0.62 | <0.001 | -0.61 | <0.001 |
| Psychological | -0.65 | <0.001 | -0.71 | <0.001 | -0.72 | <0.001 |
| Social relationship | -0.42 | 0.002 | -0.28 | 0.030 | -0.39 | 0.004 |
| Environment | -0.43 | 0.001 | -0.32 | 0.010 | -0.40 | 0.003 |

Correlations between the SQLS-R4 and both the EUROQOL-5D-5L and the WHOQOL-BREF

*Rho: Spearman's Rho correlation

groups. QL was lower (more limitations) in patients with a higher level of depression in both groups for psychosocial, vitality and total SQLS-R4 scales. QL was related to the number of acute episodes and time since diagnosis only in the group of patients with schizoaffective disorders (the greater the number of years, the lower the level of QL limitations in vitality; also, the greater the number of acute episodes the higher the level of QL limitations for the total score and marginally for the two subscales). For this group of patients with schizoaffective disorders, there were also more limitations in vitality when the negative symptoms were higher (see Annex 2).

CONCLUSION

In this paper we have presented the results of a validation study of the SQLS-R4 questionnaire for Spain performed in a sample of schizophrenia spectrum outpatients with stable disease. The high levels of patient compliance (95.4%), the low number of missing items, and the variety in level of studies represented in the sample indicate that the questionnaire was well accepted. The high percentage of patients living with their families of origin may be an issue specific to our country.

The wide distribution of the scores in the SQLS-R4, with most QL levels represented, and the low levels of the floor and ceiling effects indicate that the questionnaire has a high sensitivity. A wide range of scores and low or no floor and ceiling effects were also found in studies performed in other European countries such as Macedonia¹⁶and in other cultural areas: Malaysia¹⁷ and Taiwan¹⁸.

The mean scores in the SQLS-R4 in our sample show patients have moderate QL limitations. These mean scores are similar to those found in other European studies, such as one conducted in the UK that included outpatients and inpatients¹², and another conducted on outpatients with prominent negative symptoms from several cultural areas (including European countries)³⁴. Our scores in vitality were slightly worse (10 points) and our scores in psychosocial feelings were similar to those from a study performed with outpatients from Macedonia¹⁶. Scores in vitality and psycho-

Table 5

Association between independent factors and subjective quality of life

| | SQLS-R4 | | | | | | | |
|--|----------------------|--------|----------------------|--------|----------------------|--------|--|--|
| | Psychosocial | Р | Vitality | Р | Total | Р | | |
| Age (years) | 0.86 (-0.22;0.39) | 0.58 | 0.14 (-0.13;0.41) | 0.31 | 0.14 (-0.18;0.39) | 0.46 | | |
| Male (versus female) | 0.41 (-6.67;7.50) | 0.91 | -0.53 (-6.74;5.68) | 0.87 | 0.07 (-6.43;6.56) | 0.98 | | |
| Unemployed versus others | 2.86 (-4.22;9.95) | 0.43 | 4.85 (-1.71;11.41) | 0.15 | 4.14 (-2.29;10.58) | 0.21 | | |
| Time since diagnosis | 0.19 (-0.24;0.63) | 0.37 | 0.23 (-0.14;0.59) | 0.21 | 0.21 (-0.18;0.61) | 0.29 | | |
| Number of acute episodes | 1.85 (0.25;3.45) | 0.02 | 1.92 (8.52;3.31) | 0.008 | 1.87 (0.43;3.32) | 0.01 | | |
| Schizophrenia vs schizoaffective disorder | -12.99(-20.29;-5.70) | 0.001 | -18.47(-36.78;-0.16) | <0.001 | -12.59(-19.19;-5.98) | 0.001 | | |
| SANS | -0.38 (-0.45;1.20) | 0.36 | 0.68 (-0.05;1.40) | 0.07 | 0.50 (-0.25;1.25) | 0.19 | | |
| Calgary | 2.41 (1.74;3.07) | <0.001 | 1.87 (1.25;2.48) | <0.001 | 2.22 (1.62;2.83) | <0.001 | | |
| B values (95% Cl); B values in bold: a significant relationship was found between an independent factor and a subjective QL area | | | | | | | | |

social feelings were slightly worse in our study (7-14 points lower in the QL areas) than in two studies conducted in different cultural areas: Malaysia¹⁷ with outpatients and Taiwan²⁰ with inpatients and outpatients. A study conducted in Korea with outpatients³⁵ found better vitality (7 points better) and lower psychosocial feelings (8 points worse). Our scores in the SQLS-R4 were slightly better than those from a study conducted in Taiwan¹⁸ on inpatients with non-symptom remission (>8 points in psychosocial, vitality and total QL).

Multi-trait scaling analyses confirmed the two multiitem sub-scale structure of the questionnaire. This two-factor structure was also found in a study performed in the UK¹². Kuo et al.²⁰ found seven factors in their factor analysis performed with data from Taiwanese patients. These authors indicate that there could be some overlapping among their factors. Limitations in item 7 in the convergent analyses were small and also appeared in studies performed in Macedonia¹⁶, Taiwan¹⁹ and Malaysia¹⁷. Items that did not fulfill the item *discriminant validity* were close to the criteria.

The internal reliability for the two subscales and the global scale was very satisfactory. High Alpha coefficients were also found in studies performed in the UK¹², Macedonia¹⁶, Taiwan^{18,19} and Malaysia¹⁷. In all these studies, as in our case, the Alpha coefficient was slightly higher for the psychosocial subscale. Test-retest reliability could be considered excellent. High correlations between the test and retest assessments were also found in Taiwan¹⁹.

Convergent and divergent validity analyses with the EUROQOL-5D-5L were satisfactory. The highest correlations were found between the SQLS-R4 psychosocial feelings, vitality and Global score, and the EUROQOL-5D-5L dimension whose content may be more related: anxiety/depression, since SQLS-R4 evaluates specific aspects of schizophrenia. On the other hand, some of the lowest correlations were found between the SQLS-R4 psychosocial feelings, vitality and Global score, and the EUROQOL-5D-5L dimensions whose content may be less related: mobility and self-care. SQLS-R4 Global score also had high correlations with EURO-QOL-5D-5L health and value.

Correlations between the SQLS-R4 psychosocial feelings and vitality areas, and the EUROQOL-5D-5L were slightly higher in our study than in a Malaysian study also performed in outpatients with stable disease¹⁷. As in our case, the higher correlations were found among the psychosocial feelings and vitality subscales and the anxiety/depression EURO-QOL-5D-5L dimension.

Convergent and divergent validity analyses with the WHOQOL-BREF were also satisfactory. The highest correlations were found among areas whose content may be more related, e.g. SQLS-R4 vitality, psychosocial feelings and Global score with WHOQOL-BREF psychological domain; and

vitality with WHOQOL-BREF physical domain. Conversely, areas with the least in common had the lowest correlations, e.g. SQLS-R4 vitality area and the WHOQOL-BREF social relationship domain. Correlations between the SQLS-R4 and the WHOQOL-BREF were in line with those found in patients from Taiwan with stable disease. In that study higher correlations were found between the SQLS-R4 vitality subscale and Global score, and the WHOQOL-BREF environment domain than in our case¹⁸.

Known group validity analyses were generally supported by the data. As expected, higher QL was found among patients with lower depression, fewer acute episodes and with a diagnosis of schizophrenia.

A higher level of depression was associated with lower QL in another study performed with the SQLS-R4 in Taiwanese patients²⁰, and also with Spanish outpatients (using a different QL questionnaire)³⁹. Better QL in patients with fewer acute episodes has also been found in Taiwanese patients (SQLS-R4 questionnaire)¹⁸. Higher QL in patients with schizophrenia compared with schizoaffective disorder was also found in an Italian study (in which WHOQOL-BREF was administered)³².

With regard to the other socio-demographic characteristics, also as expected no differences were found between gender-based groups. No relation between gender and the SQLS-R4 was found in other studies performed in Korea¹⁵ or Taiwan²⁰, or in other studies that included Spanish patients and other QL questionnaires⁸. Other studies performed with the SQLS-R4 questionnaire in Taiwan²⁰ and Korea¹⁵ found no age-based differences. Lanfredi et al.³⁰, on the other hand, did find age-based differences but their patients had a different mean age than ours (and their study administered the WHOQOL-BREF questionnaire).

No differences were found between groups based on employment status. Other studies have found higher QL scores in employed patients than in patients without a job. However, our analyses included more categories in the employed patients group (students, pensioners, and patients on sick leave). Higher QL has been related to being employed in outpatients from 10 countries (including Spain)^{31,34}, outpatients from France³⁷, and outpatients from another cultural area (Taiwan)³⁸: in all these studies other QL questionnaires were administered. There was a high percentage of unemployed patients in our sample, an issue which may be specific to our cultural area.

We found no differences based on time since diagnosis. It was hypothesized that a higher QL in patients with more time since diagnosis may be expected due to a process in which patients adapt to their situation². However, in our case, and in other studies performed with the SQLS-R4 questionnaire in Taiwan²⁰ and Korea¹⁴ in which no differences were found, patients had a long period of time since diagnosis. We might understand that most of them had had time for adaptation.

Unlike what we had hypothesized, no significant relationship was found between negative symptoms and any QL area. In line with our study, Taha et al.¹⁷ found low correlations between the SQLS-R4 and negative symptoms in Malaysian outpatients. Unlike our study, negative symptoms also appeared as determinants of lower QL in other studies conducted on outpatients from our cultural area in which general QL questionnaires (WHOQOL-BREF, EUROQOL-5D5L) were administered^{8,33}.

Savill et al.40 considered that the relationship between QL and negative symptoms may depend on who assesses QL. These authors believe there is evidence of a strong association between negative symptoms and objective QL (i.e. assessed by a professional) but that the association between negative symptoms and subjective QL (i.e. assessed by the patient) is weaker. This may be because subjective QL is determined by multiple processes that include: patients comparing their expectations and the limitations created by the disease (they may expect the disease to create limitations); patients comparing their situation with that of others with the same diagnoses (they may understand their limitations are similar to those of others in their situation); and a process of adaptation over time to their situation. All the above may result in a less negative appraisal by individuals with chronic schizophrenia. In this context, Tomotake et al.41 found negative symptoms were more related to objective QL (assessed by professionals using the SQL questionnaire) than to subjective QL (assessed by the patient using the SQLS questionnaire).

Known group validity analyses in the two diagnostic groups analyzed separately showed more significant relations in the schizoaffective disorder group than in the schizophrenia group with regard to time since diagnosis, the number of acute episodes, and the level of negative symptoms. The significant relations between the number of acute episodes and QL decreased when we studied the known groups comparison in the samples of patients with schizophrenia and schizoaffective disorders separately. This may be due to a decrease in the potency of the analyses due to the smaller sample sizes. Negative symptoms are related to just one QL area, and only in patients with schizoaffective Annex 1

Sociodemographic, clinical characteristics and Quality of Life of the two diagnosis groups

| | | Schizop (n=1 | ohrenia 05) | Schizoaffective disorder (n=63) | | |
|----------------------------|----------------------------|-----------------|----------------|------------------------------------|-------|---------------------------|
| | Characteristics | Nc | % | Nc | % | Р |
| Gender | Female | 48 | 45.7 | 32 | 50.8 | 0.30ª |
| | Male | 57 | 52.3 | 31 | 49.2 | |
| Present age | Mean, SD | 37.6 | 11.7 | 42.5 | 9.7 | 0.02 ^b |
| Level of study | Less than compulsory | 16 | 15.2 | 4 | 6.3 | 0.12ª |
| | compulsory | 37 | 35.2 | 29 | 46.1 | |
| | ≥compulsory & < university | 35 | 33.3 | 24 | 38.1 | |
| | University | 17 | 16.3 | 6 | 9.5 | |
| Cohabitance | Alone | 16 | 15.2 | 7 | 11.1 | 0.90ª |
| | Partner | 8 | 7.6 | 7 | 11.1 | |
| | Partner and children | 4 | 3.8 | 6 | 9.5 | |
| | Family of origin | 62 | 59.1 | 38 | 60.4 | |
| | Other | 15 | 14.3 | 5 | 7.9 | |
| Employment status | Student | 4 | 3.8 | 1 | 1.6 | 0.02 ^a |
| | Working | 3 | 2.8 | 2 | 3.2 | |
| | Sick leave | 12 | 11.4 | 8 | 12.7 | |
| | Unemployed | 52 | 49.5 | 18 | 28.6 | |
| | Pensioner | 34 | 32.5 | 34 | 53.9 | |
| Economic income | Mean, SD | 666.1 | 558.1 | 796.6 | 731.2 | 0.12 ^b |
| N of acute episodes | Mean, SD | 2.7 | 1.9 | 4.4 | 3.2 | 0.008 ^b |
| Time since diagnoses (yrs) | Mean, SD | 12.1 | 10.6 | 14.9 | 10.2 | 0.08 ^b |
| SANS | Mean, SD | 9.5 | 4.9 | 8.0 | 4.8 | 0.16 ^b |
| Calgary | Mean, SD | 5.6 | 4.6 | 6.8 | 5.8 | 0.44 ^b |
| SQLS-R4 | | | | | | |
| Psycho-social | Mean, SD | 31.5 | 20.5 | 44.6 | 20.7 | <0.001 |
| Vitality | Mean, SD | 34.9 | 17.7 | 46.9 | 18.6 | <0.001 |
| Total | Mean, SD | 32.8 | 18.4 | 45.4 | 19.1 | <0.001 |
| EUROQOL- 5D-5L | | | | | | |
| EUROQOL value | Mean, SD | 0.84 | 0.16 | 0.74 | 0.21 | 0.004 |
| EUROQOL health | Mean, SD | 66.6 | 20.8 | 55.5 | 21.7 | 0.005 |

^aChi-square

^bMann-Whitney u test

^cData are given in frequencies and percentages unless indicated as Mean and SD

Annex 2

Association between independent factors and subjective quality of life in the subsamples of patients with schizophrenia and with schizoaffective disorder

| | SQLS-R4 | | | | | | |
|--|--------------------------------|-------------|--------------------------|-------------|--------------------|-------|--|
| | Psychosocial | Р | Vitality | Р | Total | Р | |
| SCHIZOPHRENIA | | | | | | | |
| Age (years) | -0.85(-0.45;0.29) | 0.65 | -0.35(0.35;0.28) | 0.82 | -0.65(0.39;0.27) | 0.70 | |
| Male (vs. female) | 5.20(-3.31;13.91) | 0.22 | 2.05(-5.42;9.51) | 0.59 | 3.89(-3.69;11.8) | 0.30 | |
| Unemployed vs. others | -1.07(-9.63;7.48) | 0.80 | 2.22(-5.14;9.58) | 0.55 | 0.26(-7.43;7.94) | 0.95 | |
| Time since diagnosis | 0.18 (-0.68;0.32) | 0.46 | -0.19(-0.61;0.23) | 0.37 | -0.18(-0.63;0.26) | 0.40 | |
| Number of acute episodes | -0.65(-3.14;1.85) | 0.61 | -0.17(-2.30;1.91) | 0.87 | -0.46(-2.66;1.75) | 0.67 | |
| SANS | 0.47(-0.49;1.44) | 0.33 | 0.63 (-0.19;1.45) | 0.13 | 0.54(-0.32;1.39) | 0.22 | |
| Calgary | 2.51(1.59;3.43) | <0.001 | 1.75 (0.91;2.58) | <0.001 | 2.21(1.39;3.03) | 0.010 | |
| SCHIZOAFFECTIVE DISORDER | | | | | | | |
| Age (years) | 0.48 (-0.17;1.14) | 0.14 | 0.55(-0.02;1.12) | 0.06 | 0.51(-0.08;1.11) | 0.09 | |
| Male (vs. female) | -8.49(-21.22;4.23) | 0.19 | -5.51(-16.84;5.81) | 0.33 | -7.42(-19.14;4.30) | 0.21 | |
| Unemployed vs. others | -3.09(-18.12;11.93) | 0.68 | 4.36 (-9.10;17.81) | 0.52 | -0.14(-14.1;13.74) | 0.98 | |
| Time since diagnosis | 0.65 (-0.19;1.49) | 0.13 | 0.79 (0.14;1.44) | 0.02 | 0.71(-0.05;1.45) | 0.06 | |
| Number of acute episodes | 2.17 (-0.10;4.43) | 0.06 | 2.01 (-0.09;4.11) | 0.06 | 2.11(0.07;4.19) | 0.048 | |
| SANS | 0.57 (-1.14;2.27) | 0.50 | 1.51 (0.08;2.95) | 0.04 | 0.94(-0.59;2.48) | 0.22 | |
| Calgary | 1.60 (0.29;2.92) | 0.019 | 1.72 (0.55;2.88) | 0.006 | 1.77(0.54;3.01) | 0.007 | |
| B values (95% Cl); B values in bold: a s | ignificant relationship was fo | ound betwee | en an independent factor | and a subje | ective QL area | | |

disorder, have a level of significance that is very similar to the significance found in the global sample. This result agrees with the lack of relation between QL and negative symptoms found in the whole sample.

The strengths of this study are the sample size and the test-retest analyses. However, the study could have benefited from a longitudinal design measuring QL before and after an intervention so that analyses of responsiveness to change could be performed. It would also be interesting to conduct a psychometric study in patients at the acute disease stage.

In conclusion, the SQLS-R4 questionnaire demonstrated satisfactory psychometric properties when applied to a sample of schizophrenia and schizoaffective disorder Spanish patients with stable disease. Our results are in line with those of other psychometric studies performed in Europe and other cultural areas.

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CONFLICT OF INTERESTS

The authors declare they have no conflict of interest.

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