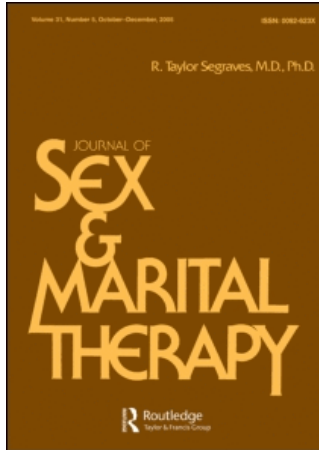


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Psychometric Properties of the Psychotropic-Related Sexual Dysfunction Questionnaire (PRSexDQ-SALSEX) in Patients with Schizophrenia and Other Psychotic Disorders

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Sexual dysfunction is a disturbing and often underrecognized problem associated with schizophrenia and its treatment. The Psychotropic-Related Sexual Dysfunction (PRSexDQ-SALSEX) is a brief and relatively nonintrusive questionnaire that has shown adequate psychometric properties in patients with depression. This study examined the psychometric properties of the PRSexDQ-SALSEX in a sample of patients with schizophrenia or other psychotic disorders who were experiencing anti-psychotic-induced sexual dysfunction and were switched to olanzapine. The PRSexDQ-SALSEX was very feasible and its internal reliability was satisfactory. In addition, this questionnaire showed a good convergent validity and sensitivity to tracking changes in sexual functioning.

Sexual dysfunction is commonly associated with psychiatric disorders, occurring not only in patients with depression but also in the course of anxiety

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disorders and schizophrenia (Segraves & Balon, 2003). In addition, although information is scanty and based largely on studies providing a low level of evidence (Rico-Villademoros & Calandre, 2005), sexual dysfunction seems to be a frequent and troublesome side effect of anti-psychotics (Bobes et al., 2003; Üçok, Incesu, Aker, & Erkoc 2007). This side effect is among the most distressing to patients with schizophrenia (Weiden & Miller, 2001, Lambert et al., 2004), is associated with low satisfaction with the treatment (Fakhoury, Wright, & Wallace, 2001), and may impair treatment compliance (Weiden, Mackell, & McDonnell 2002), leading to the stoppage of their medication one or more times during treatment in over 40% of males and 15% of females (Rosenberg, Bleiberg, Koscis, & Gross, 2003). Unfortunately, this important side effect is frequently underestimated by psychiatrists (Dossenbach et al., 2006) and is rarely spontaneously reported by patients (Knegtering et al., 2004; Montejo Gonzalez, Rico-Villademoros, Tafalla, & Majadas, 2005; Knegtering et al., 2006). Therefore, the availability of a tool for evaluating sexual functioning would be very useful for surveying this side effect both in the clinical practice and in the research setting.

When selecting appropriate rating scales for sexual functioning, several factors should be taken into account (Clayton, 2001): the instrument should address phase-specific function, be gender-specific, be brief, be perceived as nonintrusive by the patient, and monitor changes over time. Although there are other tools for evaluating sexual dysfunction, such as the Derogatis Interview for Sexual Functioning (Derogatis & Melisarotos, 1979) and the Modified Rush Sexual Inventory (Rao, Zajecka, & Skubiak, 2005), in randomized controlled trials of anti-psychotics that evaluated sexual functioning, the following instruments have been used: the Anti-psychotics and Sexual Functioning Questionnaire (Knegtering et al., 2004, 2006), the Changes in Sexual Functioning Questionnaire (Kelly & Conley, 2006), the Global Impressions of Sexual Function (Kinon, Ahl, Liu-Seifert, & Maguire, 2006), the Arizona Sexual Experience Scale (Byerly, Nakonezny, Bugno, Boles, & Rush, 2006b), the Dickson & Glazer Scale for the Assessment of Sexual Functioning (Costa et al., 2007), and the Psychotropic-Related Sexual Dysfunction Questionnaire (Keefe et al., 2004; Ciudad, Alvarez, Bousono, Olivares, & Gomez, 2007).

The Anti-psychotics and Sexual Functioning Questionnaire (ASFQ) (Knegtering, van der Moolen, Castelein, Kluiter, & van den Bosch, 2003) is a brief semi-structured interview based on the items of the Udvalg for Kliniske Undersogelser [UKU] Side Effect Rating Scale (Lingjaerde et al., 1987). Although it has been employed by its authors in two randomized controlled trials in patients with schizophrenia (Knegtering et al., 2004, 2006), as far as we know, no information is available on its psychometric properties. The Changes in Sexual Functioning Questionnaire (CSFQ) is a tool widely used for the assessment of sexual function that originally consists of 36 questions for males and 35 for females. The CSFQ has been adequately validated in patients

with depression both in the original English version (Clayton, McGarvey, & Clavet, 1997a; Clayton, McGarvey, Clavet, & Piazza, 1997b) and in the Spanish version (Bobes et al., 2000, 2002). Recently, a 14-item English version of the CSFQ has shown a good construct validity and internal reliability in patients with depression (Keller, McGarvey, & Clayton, 2006). No data are available on the CSFQ's properties in patients with schizophrenia. The Global Impressions of Sexual Function is a self-administered four-item scale that seems to have been used for an ad-hoc evaluation in a single clinical trial (Kinon et al., 2006). The Arizona Sexual Experience Scale (ASEX) is a five-item scale that has shown an excellent internal consistency and reliability, and a strong test-retest reliability in patients with depression (McGahuey et al., 2000). Although its sensitivity to change has not been formally tested, data from its extensive use in interventional studies suggest that the ASEX can also effectively measure changes in sexual function over time (McGahuey et al., 2000). The ASEX also has a good internal consistency and construct validity for the patients with schizophrenia and schizoaffective disorder (Byerly et al., 2006a). The Dickson & Glazer Scale for the Assessment of Sexual Functioning (DGSASF) is a relatively lengthy (32 items for males) self-report, computer-administered questionnaire that has been used in a randomized trial of olanzapine in males with schizophrenia (Costa et al., 2007). Although it seems that the DGSASF has been formally tested (Dickson & Glazer, 2000), there is no information on its psychometric properties. With the exception of the CSFQ, none of the above instruments has a Spanish validated version.

The Psychotropic-Related Sexual Dysfunction Questionnaire (PRSexDQ-SALSEX) is a brief, clinician-administered, and relatively nonintrusive questionnaire developed by our research group that has shown adequate psychometric properties in patients with depression (Montejo et al., 2000b). The PRSexDQ-SALSEX has been successfully used to assess sexual functioning in clinical studies of patients with depression (Montejo, Llorca, Izquierdo, & Rico-Villademoros, 2001) or schizophrenia (Montejo, Rico-Villademoros, Tafalla, Majadas, & Spanish Working Group for the Study of Psychotropic-Related Sexual Dysfunction 2005; Ciudad et al., 2007). The aim of this study was to examine the psychometric properties of this questionnaire in patients with schizophrenia or other psychotic disorders.

METHODS

Study Design and Population

The data for this analysis come from a multicenter, noncomparative, open-label, and naturalistic study where patients experiencing anti-psychotic-induced sexual dysfunction were switched to olanzapine.

Male or female patients aged 18 years or over, with a diagnosis of schizophrenia, schizophreniform disorder, schizoaffective disorder, or

delusional disorder, as defined by the DSM-IV, who were experiencing sexual dysfunction and for whom the investigators have decided that a switch to olanzapine, as part of their normal clinical practice, should be instituted were included in this study.

Patients were excluded if they were receiving or requiring concomitant treatment with another anti-psychotic or if they were treated with other medications with well-recognized effects on sexual functioning, such as selective serotonin reuptake inhibitors, tricyclic anti-depressants, venlafaxine, a mood stabilizer, anti-hypertensives, or H2 blockers. Patients were also excluded if they were current users of recreational drugs or were suffering from medical illnesses that could affect sexual functioning including diabetes, hypertension, primary hyperprolactinemia, prostatic cancer, asthma, chronic obstructive pulmonary disease, and myocardial infarction.

All patients gave their informed consent to participate. The study was reviewed and approved by the Ethics Committee of the Hospital Universitario de Salamanca (Spain) and was carried out in accordance with the Declaration of Helsinki.

Study Procedures and Assessment Tools

After the fulfilment of eligibility criteria was ensured, patients received open treatment with olanzapine and were followed for 6 months through six visits: at baseline, 2 weeks, 6 weeks, 12 weeks, and 24 weeks.

Sexual functioning was evaluated at baseline and at each study follow-up visit using the PRSexDQ-SALSEX. The PRSexDQ-SALSEX consists of seven items pertaining to sexual dysfunction (see Appendix 1). The first item is a screening item to assess whether the patient has any sort of sexual dysfunction (SD). The second item assesses whether the patient has spontaneously reported any SD to his or her physician. The next items (items 3–7) assess five dimensions of SD according to severity or frequency: loss of libido (0 = nil, 1 = mild, 2 = moderate, 3 = severe), delayed orgasm or ejaculation (0 = nil, 1 = mild, 2 = moderate, 3 = severe), lack of orgasm or ejaculation (0 = never, 1 = occasionally, 2 = often, 3 = always), erectile dysfunction in men/vaginal lubrication dysfunction in women (0 = never, 1 = occasionally, 2 = often, 3 = always), and patient's tolerance of the SD (0 = no sexual dysfunction, 1 = good, 2 = fair, 3 = poor). Only items 3 through 7 account for the total score of the PRSexDQ-SALSEX (total score ranges from 0 to 15). A full description of the PRSexDQ-SALSEX can be found elsewhere (Montejo et al., 2000b; Montejo et al., 2001). In patients with depression, the questionnaire has shown excellent feasibility and internal reliability with a Cronbach's alpha of 0.93 (Montejo et al., 2000b). It has also shown a good convergent and discriminant validity as well as being sensitive for detecting changes in sexual function (Montejo et al., 2000b). In addition, a Clinical Global Impression (CGI) of sexual functioning was used. This CGI of sexual functioning

(CGI-SF) is an ad-hoc clinician-rated instrument that is identical to the CGI used for the assessment of psychopathology (Guy, 1976). As such, the severity of sexual dysfunction is rated in a seven-point subscale (1 = normal, 7 = among the most severely ill) and global improvement of sexual function is also rated in a second seven-point subscale (1 = very much improved, 7 = very much worse).

The psychopathology was assessed using the Brief Psychiatric Rating Scale (BPRS) and the Clinical Global Impression scale. With the exception of baseline data, no information is provided about the course of the psychopathology in this report.

Statistical Analysis

Demographic and baseline clinical characteristics were described using the mean and standard deviation for continuous variables (e.g., age, PRSexDQ-SALSEX score), and the frequency and percentage for categorical variables (e.g., sex).

The feasibility of the PRSexDQ-SALSEX was assessed by analyzing the proportion of patients with missing responses. The internal reliability was assessed with the Cronbach's alpha analysis. The convergent validity of the PRSexDQ-SALSEX was assessed by performing correlations between PRSexDQ-SALSEX item scores and the score of the CGI-severity of sexual dysfunction. We also analyzed whether the scale was able to discriminate between patients with mild-to-moderate sexual dysfunction and patients with severe sexual dysfunction as measured with the CGI-severity of sexual dysfunction. Sensitivity to change was evaluated analyzing within group changes from baseline to endpoint in the PRSexDQ-SALSEX scores; in addition, the effect size was obtained by calculating the difference between the mean values of PRSexDQ-SALSEX scores before and after treatment divided by the standard deviation of that measure before treatment (Kazis, Anderson, & Meenan, 1989).

RESULTS

Patient Disposition and Characteristics

A total of 45 patients were included in the study and in this analysis. Most patients were males (82%), mainly diagnosed with schizophrenia, and were mildly-to-moderately ill. Demographic and clinical characteristics are shown in Table 1.

Feasibility and Internal Reliability

There were not unanswered items for the PRSexDQ-SALSEX at baseline. The Cronbach's alpha for the questionnaire as a whole was 0.68. We also

TABLE 1. Demographic and Clinical Characteristics

Characteristic/Variable	N = 45
Age (years), mean (SD)	36.5 (8.3)
Sex, n (%)	
Men	37 (82.2)
Women	8 (17.8)
DSM-IV diagnosis, n (%)	
Schizophrenia	31 (68.9)
Schizophreniform disorder	5 (11.1)
Schizoaffective disorder	2 (4.4)
Delusional disorder	7 (15.6)
Duration (years) of illness, mean (SD)	11.4 (7.7)
Psychopathology scales, mean (SD)	
BPRS total score	34.0 (10.7)
CGI severity	3.3 (1.1)
Sexual function scales, mean (SD)	
PRSexDQ-SALSEX total score	10.6 (2.8)
CGI-SF severity	4.8 (0.9)

BPRS = Brief Psychiatric Rating Scale; CGI = Clinical Global Impression; CGI-SF = Clinical Global Impression of Sexual Functioning; PRSexDQ-SALSEX = Psychotropic-Related Sexual Dysfunction Questionnaire; SD: standard deviation.

calculated the Cronbach's alpha by omitting each item from the questionnaire one at a time; the resulting Cronbach's alpha was 0.62 deleting item 1 (decreased libido), 0.57 deleting item 2 (delayed ejaculation/orgasm), 0.64 deleting item 3 (lack of ejaculation/orgasm), 0.61 deleting item 4 (erectile/vaginal lubrication dysfunction), and 0.66 deleting item 5 (tolerance of sexual dysfunction).

Validity

The items on the PRSexDQ-SALSEX correlated significantly with the CGI-SF severity scale as indicated in Table 2. The correlation was greater for the total score of the PRSexDQ-SALSEX. The PRSexDQ-SALSEX was also able

TABLE 2. Correlations Between PRSexDQ-SALSEX and the Clinical Global Impression of Sexual Functioning

PRSexDQ-SALSEX Items	<i>r</i>	<i>p</i>
Loss of libido	.367	0.013
Delayed ejaculation/orgasm	.539	0.000
Lack of ejaculation/orgasm	.613	0.000
Erectile/vaginal lubrication dysfunction	.446	0.002
Patients' tolerance of the sexual dysfunction	.468	0.001
PRSexDQ-SALSEX total score	.729	0.000

PRSexDQ-SALSEX = Psychotropic-Related Sexual Dysfunction Questionnaire; *r* = Spearman correlation coefficient.

TABLE 3. Change From Baseline in the PRSexDQ-SALSEX Scores (N = 44)

PRSexDQ-SALSEX Score	Baseline Mean \pm SD	Endpoint Mean \pm SD	<i>p</i>	Effect Size
Total				
Overall	10.6 \pm 2.8	2.5 \pm 3.2	<0.001	2.89
Males (n = 36)	10.1 \pm 2.9	2.3 \pm 3.2	<0.001	2.69
Females (n = 8)	12.9 \pm 4.1	3.4 \pm 2.9	<0.001	2.31
Loss of libido	1.8 \pm 1.1	0.5 \pm 0.8	<0.001	1.18
Delayed orgasm/ejaculation	2.3 \pm 0.8	0.5 \pm 0.8	<0.001	2.25
Lack of orgasm/ejaculation	2.0 \pm 1.0	0.4 \pm 0.7	<0.001	1.60
Erectile/vaginal lubrication dysfunction	1.9 \pm 0.7	0.4 \pm 0.6	<0.001	2.14
Patients' tolerance of the sexual dysfunction	2.5 \pm 0.6	0.7 \pm 0.8	<0.001	3.00

PRSexDQ-SALSEX = Psychotropic-Related Sexual Dysfunction Questionnaire; SD = standard deviation.

to discriminate between patients with mild-to-moderate sexual dysfunction (i.e., patients with a CGI-SF severity score equal to or less than 4; $n = 18$) and those with severe sexual dysfunction (i.e., patients with a CGI-SF severity score equal to or greater than 5; $n = 27$); patients with mild-to-moderate sexual dysfunction had a PRSexDQ-SALSEX total score of 8.6 ± 2.5 , while patients with severe sexual dysfunction had a score of 12.1 ± 2.1 , with these differences being statistically significant ($p < 0.001$).

Sensitivity to Change

Patients showed a significant reduction from baseline to the study endpoint in the PRSexDQ-SALSEX total score (Table 3). This significant reduction was seen both in males and females and for every single item (Table 3). Analysis of the effect size showed that a large effect size was obtained for the change from baseline in the PRSexDQ-SALSEX total score at each study visit.

DISCUSSION

Sexual dysfunction is a frequent and very relevant issue affecting treatment adherence among patients with schizophrenia that is, unfortunately, difficult to measure due to the almost lack of validated instruments for this population. Our findings indicate that the PRSexDQ exhibits good psychometric properties in patients with schizophrenia. The feasibility of the PRSexDQ-SALSEX was very good, with no missing values at baseline. The internal reliability of the PRSexDQ-SALSEX for this sample of patients with schizophrenia was satisfactory for its use as a research tool (Cronbach's $\alpha \approx 0.70$). However, it should be considered relatively low for its use in the clinical practice where the value of the questionnaire for an individual is

of interest and, therefore, higher values of alpha are desirable (Cronbach's $\alpha \geq 0.90$) (Bland & Altman, 1997). In fact, our results are not consistent with our previous report in patients with depression, where we found a much higher Cronbach's alpha of 0.93 (Montejo et al., 2000b), indicating that there is room for improvement in this regard. Nevertheless, important clinical and psychopathological differences between patients with depression and patients with schizophrenia should be taken into account in order to capture the meaning of sexual function for each patient. All items of the PRSexDQ-SALSEX seem to be equally relevant since the Cronbach's alpha after omitting item by item from the questionnaire was always lower than that of the whole questionnaire.

Analysis of the correlations between PRSexDQ-SALSEX and the CGI-SF showed a moderate correlation for the items of libido, arousal, and patients' tolerance of sexual dysfunction; there were substantial correlations for the two items measuring ejaculation/orgasm, and high correlations for the total score of the PRSexDQ-SALSEX. Overall, this analysis indicates that the PRSexDQ-SALSEX has a good convergent validity. A limitation of this analysis was the scale we selected for comparing the PRSexDQ-SALSEX. We chose the CGI-SF because of the recognized lack of a gold standard for assessing sexual dysfunction (Derogatis, Fagan, & Strand, 2000) and because our research group is quite familiar with the CGI-SF since it has been used in most of our studies (Montejo et al., 1998, 1999a, 1999b; Montejo, Llorca, Izquierdo, and the Spanish Working Group for the Study of Psychotropic-Related Sexual Dysfunction, 2000a; Montejo et al., 2000b, 2001, 2005). The good convergent validity was reinforced by the fact the PRSexDQ-SALSEX was able to detect the expected changes in sexual functioning after the switch to olanzapine.

In addition to the above-mentioned limitations, one should bear in mind that the sample size was small and the population included was composed mainly of males with schizophrenia who were experiencing anti-psychotic-induced sexual dysfunction. Therefore, the psychometric properties of the PRSexDQ-SALSEX should be further studied in larger samples of patients with schizophrenia that include medicated and unmedicated patients as well as patients with and without sexual dysfunction. Although this report is not focused on the effectiveness of switching to olanzapine as a therapeutic strategy for anti-psychotic-induced sexual dysfunction, when evaluating changes from baseline to endpoint in the PRSexDQ-SALSEX scores, it should bear in mind that our study was uncontrolled and that there was no analysis addressing improvements in psychotic illness as a potential reason for improvement in sexual function. Despite these limitations, our results suggest that the PRSexDQ-SALSEX provides a feasible and easy to score and interpret measure of the sexual functioning in patients with schizophrenia, which has an acceptable internal reliability, a good convergent validity, and is sensitive to change.

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Appendix 1. Psychotropic-Related Sexual Dysfunction Questionnaire (PRSexDQ-SALSEX)

The following questions refer to the possible appearance of sexual dysfunction after initiating treatment with psychotropic agents.

- A. Have you observed any type of change in your sexual activity (excitation, erection, ejaculation, or orgasm) since you began taking the drug treatment?
 YES
 NO
- B. Has the patient spontaneously reported this alteration or was it necessary to expressly question him or her to discover the sexual dysfunction?
 YES It was spontaneously reported.
 NO It was not spontaneously reported.
1. Have you observed any decrease in your desire for sexual activity or in your interest in sex?
 0. No problem
 1. Mild decrease. Somewhat less interest.
 2. Moderate decrease. Much less interest.
 3. Severe decrease. Almost none or no interest.
2. Have you observed any delay in ejaculation/orgasm?
 0. No delay
 1. Mild delay or hardly noticeable
 2. Moderate delay or clearly noticeable
 3. Intense delay, although ejaculation is possible
3. Have you observed that you are unable to ejaculate/or to have an orgasm once you begin sexual relations?
 0. None.
 1. Sometimes: less than 25% of the time.
 2. Often: 25–75% of the time.
 3. Always or almost always: more than 75% of the time.
4. Have you experienced any difficult obtaining an erection or maintaining it once you have initiated sexual activity? (vaginal lubrication in women)
 0. Never.
 1. Sometimes: less than 25% of the time.
 2. Often: 25–75% of the time.
 3. Always or almost always: more than 75% of the time.

Appendix 1. Psychotropic-Related Sexual Dysfunction Questionnaire (PRSexDQ-SALSEX)
(Continued)

5. How well have you tolerated these changes in your sexual relations ?
- 0. No sexual dysfunction
 - 1. Well. No problem due to this reason.
 - 2. Fair. The dysfunction bothers him or her although he or she has not considered discontinuing the treatment for this reason. It interferes with the couple's relationship.
 - 3. Poor. The dysfunction presents an important problem. He or she has considered discontinuing treatment because of it or it seriously interferes with the couple's relationship.
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