Title:

Patient rated versus clinician rated side effects of drug treatment in schizophrenia - clinical validation of a self-rating version of the UKU Side Effect Rating Scale (UKU-SERS-Pat)

Running head:

UKU-SERS-Pat

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Abstract

Lindström E, Lewander T, Malm U, Malt UF, Lublin H, Ahlfors UG. Patient rated versus clinician rated side effects of drug treatment in schizophrenia - clinical validation of a self rating version of the UKU Side Effect Rating Scale (UKU-SERS-Pat). Nord J Psychiatry 2001;xx:xxx-xxx.

A self-rating version of the UKU Side Effect Rating Scale has been developed. The present study examines the agreement between patients' self-assessment of side effects and the attending clinicians' ratings. The patient sample consisted of 63 patients with schizophrenia under maintenance treatment with risperidone, clozapine or classical antipsychotics. Approximately two thirds of the patients used concomitant medication with e.g. benzodiazepines, SSRIs, anticholinergics. Most inter-correlation's between scores for single, corresponding items, subscores of Psychic, Neurological, Autonomic and Other side effects, as well as the Total Score from the patient version of the UKU Side Effect Self Rating Scale (UKU-SERS-Pat) and the clinician version (UKU-SERS-Clin) were found to be statistically significant. Patients reported side effects more frequently and/or rated symptoms more severe than the clinicians. The results support the validity of the SERS-Pat and suggest that patient rated side effects may provide important clinical information not detected by clinician rated interviews. Such information can be utilised both in clinical investigations, in development of treatment programs and for individual patients in clinical practice.

Key words:

Side effects, Rating scale, Self rating scale, Schizophrenia, Antipsychotics

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Introduction

Side effects of drugs may impair patients' acceptance of drug treatment and compliance. In the treatment of psychotic disorders, this represents a major problem, since poor compliance reduces the effectiveness and the prognosis of serious disorders like schizophrenia (1, 2). Thus, reliable and valid assessment methods to identify side effects are needed. Different rating scales have been constructed for the measurement of side effects, some of them comprehensive and others more specific. Comprehensive scales are recommended in the evaluation of side effects in the early stage of drug testing. Among the observer rating scales of the comprehensive type, the UKU Side Effect Rating Scale constructed by the UKU (Udvalg for Kliniske Undersøgelser, Scandinavian Society for Psychopharmacology, (3)) is often used. Assessment of operationally defined severity scores of individual symptoms is accomplished by using a structured interview during which the scale is completed item by item. The interview is supplemented by clinical observations. Most of the symptoms are assessed from the patients' condition during the last three days. Changes in body weight, however, need a longer observation period.

Clinician rated side effect scales are time-consuming, however. For this reason, such scales are not frequently used in daily clinical practice. By not using systematic assessments, however, the clinicians may overlook important side effects, which threaten compliance and impair the patient's quality of life. In addition, patients may perceive side effects differently than the clinician.

In this paper we present a patient self-rating version (UKU-SERS-Pat), of the UKU Side Effect Rating Scale (UKU-SERS-Clin). In the UKU-SERS-Pat version, descriptions of the symptoms under each item, and the operationally defined severity

steps in the UKU-SERS-Clin were transformed into easily understandable questions of frequency or discomfort (see Appendix). The aim of the present study was also to validate the UKU-SERS-Pat by comparing the prevalence and severity of self-reported side effects with the corresponding ratings by experienced clinicians according to the UKU-SERS-Clin in patients with schizophrenia under maintenance treatment with optimal doses of antipsychotics, with or without concomitant medication (see Methods). We also wanted to identify side effects that might be perceived differently by patients and clinicians.

Material and Methods

Patient material

A total of 63 chronic schizophrenic patients, 40 males and 23 females, diagnosed according to the DSM-III-R (4) took part in the study (Table 1). All subtypes of schizophrenia were represented. The mean age was 37,3 (SD = 10.1) years (median = 34 years, range = 21-75 years) and the mean age at first admission was 25,5 (SD = 6.8) years (median = 24 years, range = 16-48 years). Nineteen of the patients were treated with risperidone only, and 44 of the patients with other antipsychotics (clozapine or classical neuroleptics) and one or more concomitant medication (anticholinergics, benzodiazepines, lithium, antidepressants). Most patients were symptomatic to various degrees with an average score of 65 (SD = 20) points (median = 66, range = 31-125) according to the Positive and Negative Syndrome Scale for Schizophrenia (PANSS (5)).

Design of the study

The present study was performed as a naturalistic, national, multicenter, point-prevalence study. It was part of a larger investigation of the efficacy and safety of long-term treatment with risperidone. The participating patients were all treated with antipsychotics in the maintenance phase and had been on treatment for at least one year when the side effects were rated by the UKU-SERS-Clin and the UKU-SERS-Pat scales.

In the morning of the day of examination, the UKU-SERS-Pat was administered to participating patients. When the self-rating scale had been completed, an experienced clinician, accustomed to the use of UKU-SERS-Clin made the observers' ratings of side effects. The symptomatology of the disease was assessed in the same session by using the PANSS.

Rating scales

The UKU Side Effect Rating Scale - UKU-SERS-Clin

The UKU-SERS-Clin (3) is a comprehensive side effect rating scale with well-defined items and scale steps, developed to be used in clinical drug trials and in routine clinical practice. It comprises ratings (0-4) of 48 single items, a global assessment of the influence of the reported side effects on daily performance, and a statement of the effects of the adverse events on continuation of the medication. The items are clustered into four sub-groups: Psychic, Neurological, Autonomic and Other side effects.

The UKU Side Effect Self Rating Scale - UKU-SERS-Pat

The final version of the UKU Side Effect Self-Rating Scale (UKU-SERS-Pat) comprises 48 symptoms considered suitable for self-rating (see Appendix). Similarly to the SERS-Clin the items are clustered into four subgroups: Psychic, Neurological, Autonomic and Other side effects. In the SERS-Pat Other side effects are separated into three smaller groups, those occurring in both sexes and those occurring in females only or in males only. Two items in the original UKU-SERS, namely Menorrhagia and Ejaculatory Dysfunction, have been split into two separate items in order to make it easier for a patient to respond adequately. Thus, Menorrhagia and Metrorrhagia have been separated (4.7a and 4.7 b), and Ejaculatory Dysfunction and Premature Ejaculation have been separated (4.14a and 4.14b). The items Physical Dependence and Psychic Dependence in UKU-SERS-Clin were not considered suitable for self-rating, and were, therefore, omitted in UKU-SERS-Pat.

In the present study we evaluated a preliminary version of the UKU-SERS-Pat comprising 41 items (see Table 2 and 4). Items not covered in the present study were: Photosensitivity, Increased Pigmentation, Weight Gain, Weight Loss, and Headache. Also, the symptoms under the items Menorrhagia and Ejaculatory Dysfunction (see above) had not been separated. In addition to the ratings of individual items, the scores were added up as Subscores for each of the four subgroups (Psychic, Neurological, Autonomic and Other side effects) occurring in both sexes. A sum of the ratings of all items was also calculated in order to measure the Total Score.

Ethics

The study was approved by local Ethics Committees. Informed consent to take part in the present study was given by each patient (verbally and in writing).

Statistics

Differences between the clinicians' and patients' ratings were tested for statistical significance using Spearman's intercorrelation coefficient, Rho. Differences between means were calculated using the Wilcoxon Signed Rank Test.

Results

Differences in point prevalence and severity between UKU-SERS-Pat and UKU-SERS-Clin

Overall, side effects were more frequently reported according to the UKU-SERS-Pat than for the UKU-SERS-Clin (Table 2). This was also noted for sexual dysfunctions in both males and females (Table 4). Exceptions from this pattern were Concentration Difficulties, Emotional Indifference, Hypokinesia/Akinesia, Tremor, Disturbance of Micturition and Orgasmic Dysfunction (Tables 2 and 4).

Differences between mean scores, which might be caused either by differences in prevalence or severity, with respect to the patients' self ratings and the clinicians' ratings of side effects are shown in Table 2.

There was a significant difference for five items under Psychic Side Effects: Sleepiness/Sedation, Depression, Increased Duration of Sleep, Reduced Duration of Sleep and Increased Dream Activity, showing that patients scored the presence of side effects more frequently or more severe than the clinicians.

Regarding Neurological Side Effects patients rated Dystonia, Rigidity, Akathisia, and Epileptic Seizures, and the Subscore of Neurological Side Effects higher than the clinicians.

For Autonomic Side Effects, patients rated most items statistically significantly higher than the clinicians. The same was true for the Subscore of Autonomic Side Effects.
Regarding Other Side Effects, that may occur in both sexes, the patients rated three out of four items, Rash, Pruritus and Reduced Sexual Desire, and the Subscore statistically significantly more severe than the clinicians.
With respect to the Total Score there was a marked and statistically significant ($p<0.01$) difference between the patients' and the clinicians' ratings.

Intercorrelations between severity scores in patient rated (UKU-SERS-Pat) and clinician rated (UKU-SERS-Clin) side effects

Intercorrelation coefficients for all Items, Subscores and the Total Score are shown in Table 3.
Intercorrelations between single items listed under Psychic Side Effects were statistically significant at the level $p<0.01$ for all items except one (Reduced Duration of Sleep, $p<0.05$).
With respect to Neurological Side Effects only two, Hypokinesia/Akinesia and Tremor, showed a statistically significant correlation between the patient's and the clinician's ratings.
All single items listed under Autonomic Side Effects showed a statistically significant correlation between the patients' self-ratings and the clinician's ratings.
Four items listed under Other Side Effects (Rash, Pruritus, Increased Sexual Desire, and Reduced Sexual Desire) may occur in both sexes. All but one, Increased Sexual Desire, showed a statistically significant ($p<0.01$) correlation between raters.
The Subscores for Psychic, Autonomic and Other Side Effects showed significant correlations ($p<0.01$) between the patients' self ratings and the clinicians' ratings. For

Neurological side effects, however, the patients´ and clinicians´ ratings did not correlate ($r = 0.09$).

The Total Score, i.e. the summed rating scores for all individual items occurring in both sexes, showed a significant correlation between patients´ and clinicians´ ratings ($p<0.01$).

The ratings of sexual side effects occurring in males or females only are shown in Table 4.

For males, the intercorrelation was statistically significant only for Ejaculatory Dysfunction.

For females three symptoms, Galactorrhoea, Gynaecomastia and Orgasmic Dysfunction, showed a statistically significant correlation ($p<0.01$).

Discussion

The UKU Side Effect Rating Scale has been extensively validated in patients with psychosis during treatment with antipsychotic drugs (3). In the present study, therefore, patients with schizophrenia under maintenance treatment were asked to participate in testing a self-rating version of the scale as a first effort of its clinical validation. The patients were of varying ages, of both sexes and covered a wide range of severity scores on the PANSS. Most patients had a chronic course of illness, and had a long history of treatment with antipsychotic drugs. All patients were on antipsychotic drugs with or without concomitant medication.

The overall finding of the present study is a varying but statistically significant correlation between patient and clinician rated side effects. The intercorrelations

between corresponding items on the UKU-SERS-Clin and the UKU-SERS-Pat, subscores, and the Total Score, were statistically significant in most cases. The highest correlations were found for items belonging to the sub-groups Psychic and Autonomic Side Effects, and the lowest in the subgroup of Neurological Side Effects. This finding supports the criterion validity of the UKU-SERS-Pat.

There were striking disagreements between clinicians and patients' regarding the presence of Neurological Side Effects except for Hypokinesia/Akinesia and Tremor. It may be that patients interpret the descriptions of these symptoms differently than clinicians, or, that the subjective experiences of the symptoms are not incorporated in the clinicians ratings. The low correlation between Neurological Side Effect items may also be explained by the fact that the interviews were performed by many different clinicians, which were also taking their clinical observations into account. This discrepancy needs to be explored in future studies.

Patients reported the side effects more frequently and more severe than the clinicians. This may indicate that clinicians assess symptoms less distressing than patients, or that clinicians and patients interpret symptoms differently. For example, Psychic Side Effects may be rated as psychiatric symptoms by clinicians, whereas patients may rate them as side effects of the medication.

Previous self-rating scales of side effects of drugs are few and have mainly been applied in studies of schizophrenia. In order to investigate reasons for non-compliance to antipsychotics, various inventories of drug induced subjective experiences have been developed (6, 7). More recently, a self-rating scale has been developed to

measure subjective well being, including emotional and cognitive symptoms, under treatment with antipsychotic drugs (8).

Day et al (9) have developed a self-rating scale of side effects of drugs based on a modification of the UKU Side Effect Rating Scale (LUNSERS) and reported on its application in patients with schizophrenia. Correlations for individual items between LUNSERS and the UKU (SERS-Clin) ranged from 0.11 to 0.88, and the correlation between total side effects scores on the two rating-scales was 0.83. The present UKU-SERS-Pat was designed to directly correspond to the UKU Side Effect Rating Scale (UKU-SERS-Clin). UKU-SERS-Pat differs from the LUNSERS in the wording of the symptoms and severity scores and no additional unspecific distracter items were introduced. Similarly to the LUNSERS, correlation coefficients for individual items between the UKU-SERS-Pat and the UKU-SERS-Clin ranged from 0.07-0.80. The Total Score, however, correlated less well (r=0.46) as compared with LUNSERS (r=0.83). An explanation for this apparent discrepancy may be that two raters at one site rated the patients in the study by Day et al. (9), whereas several clinicians at many different sites performed the ratings. This fact might limit the interrater reliability in the present study, which was intended to be naturalistic and, thus, better reflect the conditions in ordinary clinical practice.

The present study, as well as the study by Day et al (9), shows, that self rating scales of side effects of drugs are possible to use in patients with schizophrenia including those with high severity ratings of psychotic symptoms. In addition, the present study shows that the UKU-SERS-Pat can be used successfully in a multicenter study with several clinicians involved in the UKU-SERS-Clin ratings.

It was observed in the present study, that patients with schizophrenia on antipsychotic medication rated most side effects more often and more severe than clinicians. Further studies of validation of the UKU-SERS-Pat should include patients with other psychiatric diagnoses under treatment with various psychotropic agents, patients under treatment with medications for somatic disorders, as well as unmedicated controls (patients or healthy volunteers).

In conclusion, the present self-rating version of the UKU Side Effect Rating Scale (UKU-SERS-Pat) shows satisfactory correlations with the UKU Side Effect Rating Scale (UKU-SERS-Clin) indicating that it may be a useful both as a stand-alone and as a complementary measure in clinical investigations, including effectiveness studies, analysis of the process of treatment, as well as in clinical practice. The information obtained from UKU-SERS-Pat permits monitoring of antipsychotic medication regarding drug dosing and compliance based on empirical data. Thus, the treatment with psychopharmacological medication may become a joint educational experience for clinicians and patients in optimising drug treatment in psychiatric disorders.

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Table 1
Demographic data of the present patient material.

	Years mean (SD)	**n=**	**%**
Total		63	100
Males/Females		40/23	64/36
Age	37.3 (10.1)		
Age at first admission	25.5 (6.8)		
Antipsychotics			
Risperidone		19	30
Other antipsychotics		44	70
Concomitant medication		18	29
Benzodiazepines		13	21
SSRIs*		3	5
Tricyclic antidepressants		5	8
Lithium		22	35
Anticholinergics			
Schizophrenia, subtype		1	2
Catatonic		9	14
Disorganised		19	30
Paranoid		32	51
Undifferentiated		2	3
Residual			

* Selective Serotonin Reuptake Inhibitors

Table 2

Differences in prevalence and mean severity scores between severity scores between patient rated (UKU-SERS-Pat) and clinician rated (UKU-SERS-Clin) side effects of drug treatment in patients (n=63) with schizophrenia.

Item	UKU-SERS-Pat prevalence %	UKU-SERS-Clin prevalence %	Difference in severity scores Mean (SD)	Wilcoxon Signed-rank test p<
Concentration Difficulties (1:1)	52	54	0.05 (0.90)	n.s.
Asthenia/Lassitude (1:2)	60	60	0.06 (1.00)	n.s.
Sleepiness/Sedation (1:3)	44	32	0.35 (0.90)	0.001
Failing Memory (1:4)	41	40	0.13 (0.81)	n.s.
Depression (1:5)	49	27	0.44 (0.91)	0.001
Tension/Inner Unrest (1:6)	52	51	0.05 (0.81)	n.s.
Increased Duration of Sleep (1:7)	49	27	0.27 (0.85)	0.013
Reduced Duration of Sleep (1:8)	27	13	0.21 (0.74)	0.030
Increased Dream Activity (1:9)	43	27	0.27 (0.88)	0.015
Emotional Indifference (1:10)	40	44	0.14 (0.82)	n.s.
Psychic Side Effects (1:1-1:10)	**90**	**89**	**1.69 (4.85)**	**0.013**
Dystonia (2:1)	48	5	0.71 (0.92)	0.001
Rigidity (2:2)	38	13	0.32 (0.88)	0.002
Hypokinesia/Akinesia (2:3)	33	31	0.02 (0.75)	n.s.
Dyskinesia/Hyperkinesia (2:4)	27	14	0.16 (0.75)	n.s.
Tremor (2:5)	34	36	0.02 (0.77)	n.s.
Akathisia (2:6)	46	21	0.41 (1.04)	0.002
Epileptic Seizures (2:7)	17	2	0.22 (0.73)	0.019
Paraesthesias (2:8)	19	11	0.19 (0.47)	n.s.
Neurological Side Effects (2:1-2:8)	**75**	**52**	**2.30 (4.18)**	**0.001**
Disturbance of Accommodation (3:1)	35	25	0.08 (0.68)	n.s.
	25	24	0.05 (0.79)	n.s.
Increased Salivation (3:2)	27	14	0.24 (0.71)	0.015
Reduced Salivation (3:3)	22	13	0.14 (0.47)	0.031
Nausea/Vomiting (3:4)	17	5	0.14 (0.50)	0.047
Diarrhoea (3:5)	24	14	0.19 (0.47)	0.003
Constipation (3:6)	3	6	0.05 (0.28)	n.s.
Disturbance of Micturition (3:7)	30	22	0.22 (0.77)	0.032
Polyuria/Polydipsia (3:8)	44	32	0.21 (0.70)	0.028
Orthostatic Dizziness (3:9)	22	13	0.11 (0.48)	n.s.
Palpitations/Tachycardia (3:10)	27	19	0.14 (0.56)	n.s.
Increased Sweating (3:11)				
Autonomic Side Effects (3:1-3:11)	**78**	**70**	**1.62 (2.86)**	**0.001**

Rash (4:1)	32	24	0.24 (0.56)	0.001
Pruritus (4:2)	32	16	0.16 (0.51)	0.031
Increased Sexual Desire (4:3)	10	3	0.10 (0.47)	n.s.
Reduced Sexual Desire (4:4)	40	32	0.29 (0.97)	0.025
Other Side Effects (4:1-4:4)	**66**	**48**	**1.38 (1.52)**	**0.004**
TOTAL SCORE	**94**	**94**	**6.03 (9.33)***	**0.001**

* UKU-SERS-Pat: mean (SD) 16.1 (11.3); UKU-SERS-Clin: mean (SD) 10.0 (8.0); $p<0.05$

Table 3
Intercorrelations between severity scores in patient rated (UKU-SERS-Pat) and Clinician rated (UKU-SERS-Clin) side effects of drug treatment in patients (n=63) with schizophrenia.

Item	Spearman´s Rho	p
Concentration Difficulties (1:1)	0.50	<0.01
Asthenia/Lassitude (1:2)	0.35	<0.01
Sleepiness/Sedation (1:3)	0.36	<0.01
Failing Memory (1:4)	0.44	<0.01
Depression (1:5)	0.41	<0.01
Tension/Inner Unrest (1:6)	0.48	<0.01
Increased Duration of Sleep (1:7)	0.47	<0.01
Reduced Duration of Sleep (1:8)	0.31	<0.05
Increased Dream Activity (1:9)	0.41	<0.01
Emotional Indifference (1:10)	0.33	<0.01
Psychic Side Effects (1:1-1:10)	**0.48**	**<0.01**
Dystonia (2:1)	0.11	n.s.
Rigidity (2:2)	0.13	n.s.
Hypokinesia/Akinesia (2:3)	0.36	<0.01
Dyskinesia/Hyperkinesia (2:4)	0.07	n.s.
Tremor (2:5)	0.39	<0.01
Akathisia (2:6)	0.15	n.s.
Epileptic Seizures (2:7)	0.06	n.s.
Paraesthesias (2:8)	0.23	n.s.
Neurological Side Effects (2:1-2:8)	**0.09**	**n.s.**
Disturbance of Accommodation (3:1)	0.44	<0.01
Increased Salivation (3:2)	0.80	<0.01
Reduced Salivation (3:3)	0.40	<0.01
Nausea/Vomiting (3:4)	0.71	<0.01
Diarrhoea (3:5)	0.64	<0.01
Constipation (3:6)	0.68	<0.01
Disturbance of Micturition (3:7)	0.34	<0.01
Polyuria/Polydipsia (3:8)	0.46	<0.01
Orthostatic Dizziness (3:9)	0.51	<0.05
Palpitations/Tachycardia (3:10)	0.27	<0.01
Increased Sweating (3:11)	0.55	<0.01

Autonomic Side Effects (3:1-3:11)	**0.63**	**<0.01**
Rash (4:1)	0.83	<0.01
Pruritus (4:2)	0.56	<0.01
Increased Sexual Desire (4:3)	0.24	<0.05
Reduced Sexual Desire (4:4)	0.47	<0.01
Other Side Effects (4:1-4:4)	**0.66**	**<0.01**
TOTAL SCORE	**0.46**	**<0.01**

Table 4
Differences in prevalence and intercorrrelations between patient rated (UKU-SERS-Pat) and clinician rated (UKU-SERS-Clin) sexual side effects of drug treatment in male (n=40) and female (n=23) patients wit schizophrenia.

Item	**SERS-Pat prevalence %**	**SERS-Clin prevalence %**	**Spearmans Rho**	**p**
Males				
Erectile Dysfunction (4:5)	28	19	0.29	n.s.
Ejaculatory Dysfunction (4:6)	33	27	0.32	<0.05
Females				
Galactorrhea (4:7)	13	4	0.58	<0.01
Gynecomastia (4:8)	26	0	0.78	<0.0001
Orgastic Dysfunction (4:9)	30	35	0.68	<0.01
Dry Vagina (4:10)	23	5	0.10	n.s.
Amenorrhoea (4:11)	26	23	0.13	n.s.
Menorrhagia (4:12)	22	18	0.30	n.s.

Appendix

/UKU-SERS-Pat in 6 languages - see separate file/