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Chapter 3

The Development of the Antipsychotic and Sexual Functioning Questionnaire (ASFQ)

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Data presented at the International Congress on Schizophrenia Research
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Summary

A literature review was made of questionnaires that evaluate the sexual side effects of antipsychotics. As none of the questionnaires found was suitable for studying sexual side effects in patients with schizophrenia, a new questionnaire, the Antipsychotic and Sexual Functioning Questionnaire (ASFQ) was developed. Preliminary studies on the validity and reliability of the ASFQ are presented here. Although the number of patients in these studies is still small, the data suggest that the ASFQ has an acceptable test-retest validity, modest concurrent validity, and good sensitivity for therapeutic changes with regard to most important items of sexual functioning. The ASFQ was chosen as the main instrument in the studies presented in other chapters of this thesis.
Introduction

Six years ago, when we began to study sexual side effects of antipsychotics on schizophrenic patients, validated instruments (questionnaires or interviews designed to evaluate sexual dysfunctions) were scarcely available. Reviews about validated instruments have become available only recently; these still do not provide information about their suitability for the assessment of sexual functioning in patients with schizophrenia, or about sensitivity to treatment effects (Derogatis and Laban 1998; Meston and Derogatis 2002).

Most authors reporting on the sexual side effects of antipsychotics have developed their own instruments, and do not provide information about the reliability or validity of the scales they use (Teusch et al. 1995; Aizenberg et al. 1995; Aizenberg et al. 2001). In some studies, the validated UKU side effects rating scale has been used (Hummer et al. 1999; Lingjaerde et al. 1987). The UKU is a semi-structured questionnaire designed to assess psychological, neurological, autonomic and other side effects of antipsychotics. The UKU has reliable scoring rules but no standardized questions. The UKU indicates subjects in a checklist; these subjects are to be discussed until sufficient information is obtained to score an item according to the criteria specified. The fact that the UKU does not indicate how the questions are to be asked leaves a lot of room for interviewer bias.

Burke et al. (1994) published a pilot study on a 15-item Sexual Functioning Questionnaire (SFQ) inquiring about habitual and actual sexual functioning in men on antipsychotic medication (Burke et al. 1994). Questions could be answered as true or false. Sexual functioning was rated for the past two years, the past two weeks, and the present. Patients were asked whether their present medication changed the frequency of sexual thoughts, frequency of sexual activities, or the quality of their sexual functioning. In addition, a general question was posed, whether patients’ present sexual functioning was better or worse than previously. The authors concluded that in their sample of 20 chronically hospitalized patients with schizophrenia, patients could respond consistently to simple inquiries about concrete events such as erections or masturbation, but experienced difficulties in reporting about sexual thoughts and fantasies, or reporting about overall impairment. The authors concluded that a repeat study with a larger sample-size and more rigorous statistical testing was needed.

A recent study by Smith et al. (2002), called the Sexual Functioning Questionnaire, presents 38 questions. This questionnaire is a modified version of Burke’s SPQ; Smith’s study will here be referred to as SPQ-S. The SPQ-S contains sub-scales for different areas of sexual functioning; items for women were also added. The questions can be answered true or false, and the time frame is the past month. Some information is available about the reliability of this instrument (Cronbach’s α = 0.90, Guttman’s split half reliability = 0.86); no information is available about the reliability of the SPQ-S. Both questionnaires, the SPQ and the SPQ-S, lack scoring possibilities for improvement on individual items of sexual functioning.

The lack of validated or standardized instruments makes it difficult to give a good interpretation or to compare the results of studies evaluating sexual dysfunctions in patients being treated with antipsychotics. This may partly explain why the results between studies vary a great deal. In most pre-marketing registration studies of antipsychotics, assessment of side effects is restricted to specific areas such as
extra-pyramidal side effects and acathisia, while other side effects are mainly assessed by spontaneous reports. Side effects are reported in studies using spontaneous reports, clinical interviews using questionnaires, or self-rating versions of the same questionnaires, the latter source identifying the most side effects (Lindstrom et al. 2001). As both patients and clinicians are often reluctant to discuss sexual side effects, these side effects are seldom found in general studies, whereas high frequencies are found in studies specially designed to measure sexual side effects (Knegtering et al. 2003; Peuskens et al. 1998).

When we started studies on sexual side effects of antipsychotics at the University of Groningen, we needed an instrument to assess the different phases of sexual activity: libido, arousal (erection, lubrication), orgasm and ejaculation. The instrument had to be easy to apply to clinical practice, reliable, able to detect sexual dysfunctions and changes in sexual performance, and suitable for patients with mild cognitive or psychotic symptoms.

We tried a Dutch translation of the Clayton Sexual Functioning Questionnaire (CSFQ), originally a pencil and paper questionnaire (Clayton et al. 1997). The CSFQ turned out to be too complicated for many patients with schizophrenia, as illustrated by the fact that some female patients filled in items for men. Another problem was that the questionnaire did not include a clear time frame, or items pertaining to libido. For these reasons, the CSFQ was not included in the analysis of our data.

In the course of our studies, the Dickson and Glazer Sexual Functioning questionnaire (DGSF), a computerized questionnaire designed to evaluate antipsychotic-induced sexual dysfunctions, became available (Dickson et al. 2001). We translated it into Dutch in collaboration with the authors of the DGSF (Knegtering and Castelain 2001). Although this computerized questionnaire has many advantages in terms of reliability and excludes interviewer bias, two important problems limited its usefulness: 1 If a patient indicates s/he has no partner and no sexual activity, further questioning is stopped, leading to a loss of information; 2 Items for libido and orgasm are lacking, while items on thinking about sex and satisfaction with sexual performance have been added. These additions did not correspond well with items about libido or orgasm as defined in the UKU and ASFQ. The DGSF also includes an item about overall sexual functioning, asking the patient to report changes in sexual symptoms probably linked to treatment with antipsychotic medication. In conclusion, although the DGSF has many advantages, it does not cover all phases of sexual functioning (Meston and Frohlich 2000), and the structure of the questionnaire leads to loss of data.

The items in the UKU turned out to be the most appropriate ones for our studies, and using them made it possible to compare data with other studies. However, some problems became evident during pilot studies in our clinic using the sexual side effects items on the UKU:
1. Clinicians/interviewers experienced difficulties interviewing the patients. Some of them found it difficult to introduce sexual topics to the patient and some missed guiding questions needed for an optimal interview.
2. Often interviewers asked questions in different ways; although not formally investigated, this probably affected the inter-rater reliability of the data.
3. Although the vast majority of patients reported impairments in sexual functioning, some did report improvement. However, apart from libido, the wording of the items of the UKU did not permit ratings for improvement.
4. The time frame of the questions (the past three days) was too short.

The antipsychotics and sexual functioning questionnaire (ASFQ)

In order to keep the advantages of the UKU but to eliminate its disadvantages, we developed a questionnaire based on the UKU items for sexual functioning, the Antipsychotics and Sexual Functioning Questionnaire (ASFQ) (Knegtering, H. and Castelein, S. 2001). The objective was to design a questionnaire specifically aimed at discovering the sexual side effects of antipsychotics in patients with schizophrenia and related psychotic disorders. To reduce interviewer bias, a semi-structured interview was included. Questions were to be phrased in a non-leading and understandable way. Patients with (mild) psychotic symptoms ought to be able to complete the interview. Items for men and women were to be included, covering the main areas of sexual functioning, and enabling both improvement and worsening to be scored. The questionnaire was intended to help clinicians be able to discuss sexual side effects.

Structure of UKU and ASFQ

The items in the UKU relating to sexual side effects are the following: increased sexual desire, diminished sexual desire, erectile dysfunction, ejaculatory dysfunction, orgasmic dysfunction, insufficient vaginal lubrication. Each item can be scored as 0 (no or doubtful side effect); 1 (mild side effects that do not interfere with sexual functioning); 2 (side effects that interfere moderately with the patient’s sexual functioning); or 3 (side effects that interfere markedly with sexual functioning). The time frame in the UKU is the past three days. In conclusion, the interviewer is asked to estimate the likelihood of a causal relationship between the side effects reported and the medication used, to be scored as follows: improbable; possible; probable.

The ASFQ guides interviewers in introducing the subject of sexual side effects to the patient in a normal and non-directive way. At the beginning of the interview, some basic clinical and demographic information is solicited. After a general introduction to the questionnaire, preliminary questions are provided for each item. The interviewer is instructed to continue asking questions until the answers are clear enough to permit a scoring. Rules for scoring are presented along with each individual item. The time frame of the interview is the past month.
The development of the antipsychotic and sexual functioning questionnaire (ASFQ)

The items and scores

In order to give the ASFQ a consistent structure, increased or decreased sexual desire is considered as one item, libido. This makes it possible to handle all items in the same way, offering scoring possibilities for improvement or worsening of symptoms. Each item can be scored as 0 – absent, or if present, not related to antipsychotic treatment; 1 -much decreased (severe); 2 -decreased (mild); 3 - unchanged; 4 -increased (improved); 5 -strongly increased (much improved). Items on the ASFQ included sexual desire (libido), orgasm, erectile dysfunction, ejaculatory dysfunction, and vaginal lubrication. Also included, but not within the scope of this pilot study, were amenorrhoea, dysmenorrhea, galactorrhea, gynaecomastia.

Psychometric properties of the ASFQ, a pilot study

We conducted a pilot study on the reliability and the validity of the ASFQ. Reliability and validity are important concepts for assessing a questionnaire. Test-retest reliability, inter-rater reliability, concurrent reliability, and sensitivity to change are important criteria in evaluating questionnaires like the ASFQ (Derogatis and Laban 1998; Kluitert and Ormel 1999). Validation studies of the ASFQ are ongoing. Preliminary data are presented on main items of the ASFQ: libido, orgasm, erection, ejaculation and a sum score indicating the presence of any sexual side effect related to the use of antipsychotics. The last category offers possibilities of comparison to the general description of sexual dysfunctions in other questionnaires. In addition, interviewers and patients were asked about their experiences with the ASFQ. Test-retest, concurrent reliability and sensitivity to change were determined.

Method

Test-retest reliability was determined by twice interviewing a group of 17 patients with an interval of one week, using the ASFQ. The criteria for inclusion were using an antipsychotic for at least six weeks, and not changing medication during the study period of six weeks, being between 17 and 42 years old, and suffering from schizophrenia, or a schizophrenia spectrum disorder. Concurrent reliability was determined by interviewing 51 patients with the ASFQ and the DGSF after six weeks of treatment with antipsychotic medication. Items with the same wording were selected for comparison. The presence of any sexual dysfunction according to the ASFQ was compared with sexual side effects experienced by patients according to the DGSF. Sensitivity for change was determined by interviewing 18 patients who experienced sexual side effects when being treated with a prolactin-elevating antipsychotic and then switched to a prolactin-sparing antipsychotic. Patients were interviewed after six weeks’ treatment with the antipsychotic medication tested. Our impression based on a collective database suggested that about 70% of the patients would improve in sexual functioning (Knegtering et al. 2003). For test-retest reliability and concurrent validity, Phi ($\phi$) was used as a regulating function. In these calculations Phi can range from -1 (a negative association), 0 (no association) to 1 (positive association).
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Results
The face validity appeared to be good. Interviewers and patients did not experience problems understanding and completing the questionnaire. The average time for completing the questionnaire was 15 minutes. Clinicians found the interview helpful in discussing sexual side effects with patients. Test-retest reliability was assessed in 17 patients with dichotomised scores of individual items: Libido $\phi = 0.627$, $p = 0.01$; Orgasm $\phi = 0.522$, $P = 0.070$; Erection $\phi = 0.542$, $P = 0.072$; Ejaculation $\phi = 0.316$, $P = 0.343$; Any sexual dysfunction $\phi = 0.633$, $P = 0.009$. Because only three women were included, vaginal lubrication could not be assessed.

Concurrent validity was gauged in 51 patients with dichotomized items of the DGSF: Erection $\phi = 0.472$ $P = 0.01$; Ejaculation $\phi = 0.289$ $P = 0.197$ and Any sexual dysfunction $\phi = 0.524$ $P = 0.000$ (Dickson et al. 2001). The conceptual differences regarding libido and orgasm hindered the comparisons of these items. Not enough women were included to evaluate the vaginal lubrication item.

To examine the sensitivity of the ASFQ to changes in antipsychotic medication, 18 patients who had reported sexual dysfunctions while on prolactin-elevating antipsychotics were changed to a prolactin-sparing antipsychotic. In 14 patients, one or more items of the ASFQ were evaluated as having improved ($\chi^2 = 5.556$, df=1, $p = 0.012$). These findings were in line with our expectation that in about 70% of the patients sexual performance would improve when switching from a prolactin-elevating to a prolactin-sparing antipsychotic. These results suggest that the ASFQ is sensitive to clinical change.

Conclusion
The ASFQ has good face validity, and offers interviewers and patients supportive guidance. Inter-rater reliability data, while important, are not yet available. The test-retest reliability is modest on the level of individual items, and acceptable on the final item (any sexual dysfunction). For concurrent validity, apart from the item on erection, the data are not convincing on individual items, and modest for the overall scores. Here the main problem was a lack of overlap between the definitions of items on the ASFQ and DGSF. The sensitivity to changes in treatment is promising. Although the number of patients in these studies is still small, preliminary data suggest that the ASFQ has an acceptable test-retest reliability, modest concurrent validity and good sensitivity for therapeutic changes for most important items of sexual functioning.
The development of the antipsychotic and sexual functioning questionnaire (ASFQ)

Reference List


Antipsychotics and Sexual Functioning Questionnaire

A.S.F.Q.

Version 2003

University Hospital Groningen, The Netherlands
Department of Psychiatry
Rikus Knegtering and Stynke Castelein

Introduction
The main aim of this questionnaire is to study the effects of antipsychotics on the sexual functioning of patients to enable a comparative study of different antipsychotics. Please fill in this questionnaire if you have been taking antipsychotics for 4 to 6 weeks, are younger than 45, and are not pregnant or lactating. The questions in bold in this questionnaire are obligatory. The interviewer may alter the phrasing of the questions, or add questions so as to clarify the meaning as desired.

- Name : 
- Patient number : 
- Name of hospital : 
- Date of birth : 
- Sex : 
- Length and height : 
  (Note length/height, in a doubtful case, measure length!)
- DSM-IV diagnosis : 
- Date : 
- Psychiatrist / physician : 

Reason for prescribing the current antipsychotic:

---------------------------------------------------------------------------------------------------------------------------

Please list here all medications taken, with dosages, prior to the current antipsychotic (note also non-antipsychotics):

---------------------------------------------------------------------------------------------------------------------------
Attachment, the antipsychotic and sexual functioning questionnaire (ASFQ)

For how long did the patient use the previous antipsychotic?
1. The patient has not used any antipsychotic in the past month
2. Less than a week
3. 1-2 weeks
4. 2-6 weeks
5. 6 weeks to 3 months
6. Longer than 3 months

Remarks:
................................................................................................................................................
................................................................................................................................................
................................................................................................................................................
What was the main reason for stopping the previous antipsychotic?
1. Another psychotic episode
2. Previous antipsychotic was not effective
3. Previous antipsychotic had unpleasant side effects
4. Scientific research
5. Other, namely ................................................................................................................................

Current antipsychotic (+ dosage) and co medication (+ dosage):
................................................................................................................................................
................................................................................................................................................
................................................................................................................................................

Can you describe the effects of the antipsychotic medication you use at present (name of medication)?
(Result of treatment. The score is based on the opinion of the patient in comparison with four to six weeks ago and the general clinical impression made on the interviewer during the conversation).

Result of treatment with antipsychotic: 0. Unknown
1. Much worse
2. Worse
3. Unchanged
4. Improvement
5. Strong improvement
Men and women

What side effects did you experience from this antipsychotic? Have you experienced any other undesirable effects from this medication? (Describe all side effects mentioned by the patient that may be related to the antipsychotic used over the past four weeks. Do not add side effects mentioned by the patient in a later phase of the interview.)

Some patients notice changes in their sexual desires and functioning after using antipsychotics. Sometimes changes are noted during sexual intercourse with a partner or during sexual self-stimulation. Some patients relate an improvement in sexual functioning, others a worsening.

Did you notice a change in your sexual desire or interest in the past 4 to 6 weeks, for example more or less interest in sex? (Continue questioning until the answer is clear or no further clarification can be obtained.

Score changes in sexual functioning that may be related to the use of this antipsychotic over the past four weeks.)

- **Unknown**: will be scored if patients are not willing or not able to answer the question, or if no clear answer can be obtained in spite of thorough questioning.
- **Much worse**: will be scored if the patient has hardly any spontaneous sexual interests and/or is suffering from decreased sexual interest.
- **Worse**: will be scored if the patient has decreased sexual interest, but the patient does not suffer from this too much.
- **Unchanged**: will be scored if there is no change in sexual interest caused by the use of antipsychotic medication, i.e. libido is normal. Some patients state they never had sexual interests, and if this has not changed, score unchanged.
- **Improvement**: will be scored if the patient mentions an improvement in sexual interest in comparison with at any time previously.
- **Strong improvement**: will be scored if the patient mentions a strong improvement in sexual interest/ desires in comparison with at any time previously, so that optimal sexual functioning is possible.

<table>
<thead>
<tr>
<th>Change in interest in sex</th>
<th>0.</th>
<th>1.</th>
<th>2.</th>
<th>3.</th>
<th>4.</th>
<th>5.</th>
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<tbody>
<tr>
<td></td>
<td>Unknown</td>
<td>Much worse</td>
<td>Worse</td>
<td>Unchanged</td>
<td>Improvement</td>
<td>Strong improvement</td>
</tr>
</tbody>
</table>

56
Do you think your current antipsychotic medication has affected your ability to achieve orgasm (come) in the past four to six weeks? For example, have you had difficulty achieving orgasm (coming) or have you had an orgasm (come) sooner than you wanted to? (Continue questioning until the answer is clear or no further clarification can be obtained. Score changes in sexual functioning that may be related to the use of this antipsychotic over the past four weeks.)

Unknown will be scored if patients are not willing or not able to answer the question or if no clear answer can be obtained in spite of thorough questioning. Much worse will be scored if the patient has hardly had any orgasms and/or is suffering because of being unable to ejaculate (come). Worse will be scored if the patient’s ability to ejaculate is reduced (but not absent), for example coming later than desired. Unchanged will be scored if the use of the antipsychotic has no effect on the ability to have an orgasm. Some patients state that they never have orgasms; if this has not changed, score unchanged. Improvement will be scored if the patient describes an improvement in the ability to have an orgasm in comparison with at any time previously. Strong improvement will be scored if the patient describes a strong improvement in the ability to have an orgasm in comparison with at any time previously, so that optimal sexual functioning is possible.

Change in ability to have an orgasm:

0. Unknown
1. Much worse
2. Worse
3. Unchanged
4. Improvement
5. Strong improvement

Men (women, go to page 6)

Do you think that your current antipsychotic medication affects your ability to have an erection? For example, has the time required to obtain and maintain an erection changed, or has the stiffness of the penis during an erection changed (worsened or improved)? (Continue questioning until the answer is clear or no further clarification can be obtained. Score changes in sexual functioning that may be related to the use of this antipsychotic over the past four weeks.)

Unknown will be scored if patients are not willing or not able to answer the question or if no clear answer can be obtained in spite of thorough questioning. Much worse will be scored if the patient can hardly obtain an erection and/or is suffering a lot from a reduced ability to have an erection. Worse will be scored if the ability to obtain an erection is reduced (but not absent), for example it takes longer to get an erection, there is a problem maintaining it, or if the stiffness of the penis during an erection is reduced.
Unchanged will be scored if the use of the antipsychotic seems to have no effect on the ability to have an erection. Some patients mention a problem with erection caused by a somatic problem not related to the use of the current antipsychotic, if this continues as before score unchanged. Improvement will be scored if the patient describes an improvement in the ability to have an erection in comparison with at any time previously (faster and/or longer duration and/or improved stiffness). Strong improvement will be scored if the patient describes a strong improvement in the ability to have an erection in comparison with at any time previously, so that optimal sexual functioning is possible. Priapism is an unwanted erection that is painful and lasts for over one hour without any stimulation (Note: priapism must be treated immediately).

Change in ability to have an erection: 0. Unknown 1. Much worse 2. Worse 3. Unchanged 4. Improvement 5. Strong improvement 6. Priapism

Did you notice a change in the volume of ejaculate (sperm) in the past four to six weeks? For example, was the volume of ejaculate less or more than usual? Or was ejaculation absent? (Continue questioning until the answer is clear or no further clarification can be obtained. Score changes in sexual functioning that may be related to the use of this antipsychotic over the past four weeks.)

Unknown will be scored if patients are not willing or not able to answer the question or if no clear answer can be obtained in spite of thorough questioning. Score unknown if the patient did not come (ejaculate) in the last six weeks. Much worse will be scored if there is hardly any sperm during an orgasm and/or the patient is suffering a reduced ability to produce sperm. Worse will be scored if there is a decline (but not absence) in volume of ejaculate during an orgasm. Unchanged will be scored if the use of the antipsychotic medication seems to have no effect on the volume of ejaculate. Improvement will be scored if the patient describes an increase in the volume of ejaculate during an orgasm in comparison with at any time previously. Strong improvement will be scored if the patient mentions a strong improvement in the volume of ejaculate during an orgasm in comparison with at any time previously, so that optimal sexual functioning is possible.

Women

Are you taking birth control pills?
Taking birth control pills:
0. Unknown
1. Yes
2. No

If yes, name of birth control pill……………………………………

Was your menstrual period absent during the past four to six weeks?

Absence of menstrual period:
0. Unknown
1. Yes
2. No
3. Yes, I am probably pregnant

Date of last menstruation ……/……./…………

In the past four to six weeks, have you had milk leak from your breasts? Or did you leak milk when you squeezed your nipples?

Milk leaking from breasts (galactorrhoea):
0. Unknown
1. Yes
2. No

Have you noticed a swelling of your breasts and/or nipples in the last four to six weeks?

Swelling of breasts and/or nipples:
0. Unknown
1. Yes
2. No

Do you think that your current antipsychotic medication has affected the amount of vaginal lubrication (wetness) in the last four to six weeks? For example, have you noticed during sexual intercourse or during sexual self-stimulation that the amount of vaginal lubrication has increased or decreased?
(Continue questioning until the answer is clear or no further clarification can be obtained. Score changes in sexual functioning that may be related to the use of this antipsychotic over the past four weeks.)

Unknown will be scored if patients are not willing or not able to answer the question or if no clear answer can be obtained in spite of thorough questioning.
Much worse will be scored if there is hardly any vaginal lubrication during sexual stimulation and/or if the patient is suffering because of a decrease in vaginal lubrication.
Worse will be scored if the amount of vaginal lubrication has decreased.
Unchanged will be scored if there is no change in the amount of vaginal lubrication or if the problem already existed and is probably not related to the use of the current antipsychotic.
Improvement will be scored if the patient mentions an improvement in the amount of lubrication or becomes lubricated more easily in comparison with six weeks ago.
Strong improvement will be scored if the patient mentions a strong improvement in the amount of lubrication in comparison with six weeks ago, so that optimal sexual functioning is possible.

Change in vaginal lubrication during sexual excitement:
0. Unknown
1. Much worse
2. Worse
3. Unchanged
4. Improvement
5. Strong improvement

Have you had sexual intercourse with a partner the last six weeks?
0. Yes, continue
1. No, go to page 8 (results of the laboratory research)

Did you have pain during sexual intercourse in the last four to six weeks?
(Continue questioning until the answer is clear or no further clarification can be obtained. Score changes in sexual functioning that may be related to the use of this antipsychotic over the past four weeks.)

Unknown will be scored if patients are not willing or not able to answer the question or if no clear answer can be obtained in spite of thorough questioning.
Worse means that having sexual intercourse is painful, and that this is probably related to the present antipsychotic medication.
Unchanged means the present antipsychotic medication did not result in painful sexual intercourse or painful sexual intercourse was already present before using this antipsychotic medication.
Improvement will be scored if painful sexual intercourse in the past has clearly diminished since the present antipsychotic medication.

Change of pain during sexual intercourse:
0. Unknown
1. Worse
2. Unchanged
3. Improvement