#### **BASIC SCIENCE**

# Translation and Validation of the Greek Version of the Antipsychotics and Sexual Functioning Questionnaire (ASFQ)



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# **ABSTRACT**

**Introduction:** Sexual dysfunction in patients with psychoses may be associated with the psychiatric illness itself (negative symptoms, such as apathy, and avolition), comorbid somatic health, psychosocial factors (stigmatization, discrimination), and the use of psychotropic drugs. In Greece, research into the study of antipsychotic-induced sexual dysfunction is not sufficient.

**Aim:** This study was conducted to translate and validate the Greek version of the Antipsychotics and Sexual Functioning Questionnaire (ASFQ) in a sample of patients receiving antipsychotic treatment.

**Methods:** A "forward-backward translation" method was applied. A pilot study was conducted with 15 outpatients with schizophrenia and bipolar disorder under antipsychotics treatment. Patients also completed the "Subjects' Response to Antipsychotics (SRA)" questionnaire in order to assess the validity of the ASFQ. The ASFQ and the SRA questionnaire were completed twice within 2 weeks.

Main outcome measures: Reliability (internal consistency and test-retest) and validity were assessed.

**Results:** The Greek translation of ASFQ was reliable, with excellent internal consistency (Cronbach's a = 0.90 for men and 0.95 for women in both measurements). In addition, the Spearman correlation coefficient was 1 (P< .001) in all Likert-type questions in both assessments. Finally, Spearman correlation coefficients between ASFQ and SRA were moderately positive to strongly positive (between 0.25 and 1) in both assessments, demonstrating moderate to high validity.

Conclusions: The Greek version of the ASFQ has proved to be a reliable and valid clinical instrument, hence it can be used in further studies in the Greek population. Angelaki M, Galanis P, Igoumenou A, et al. Translation and Validation of the Greek Version of the Antipsychotics and Sexual Functioning Questionnaire (ASFQ). Sex Med 2021;9:100334.

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Key Words: Translation; Validation; Sexual dysfunction; Antipsychotics; Schizophrenia

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#### INTRODUCTION

According to the 10th Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10), sexual dysfunction means that an individual is unable to participate in a sexual relationship as he or she would wish. It usually involves both psychological and physical processes. People with psychoses describe sexuality and intimacy as unsatisfactory, while the need and the desire for sexual activity do not differ significantly from the general population.

Sexual dysfunction in patients with psychoses may be associated with the psychiatric illness itself (negative symptoms, such as apathy, and avolition), comorbid somatic health, psychosocial factors (stigmatization, discrimination), and the use of psychotropic drugs.<sup>3–7</sup> Antipsychotic-induced sexual dysfunction adversely

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affects patients' treatment, as it leads to decreased adherence to pharmacotherapy and reduced quality of life.  $^{8-10}$ 

Patients and clinicians show an unwillingness and reluctance to discuss the disturbances in sexual functioning. <sup>11,12</sup> Studies have shown that the incidence of sexual dysfunction was less than 10% when patients were asked about antipsychotic-related side effects and had the opportunity to report sexual dysfunction spontaneously. On the other hand, this rose to 30%–60% at studies that have used structured interviews or self-report questionnaires. <sup>13–17</sup> According to psychiatrists, only 10% of them discuss sexual side effects of psychopharmacological treatment with patients, whereas most consider sexual side effects to be clinically relevant in the majority of patients. <sup>12</sup>

The incidence of sexual dysfunction in patients receiving antipsychotic medication varies. There are several methodological difficulties in assessing the incidence and the prevalence of sexual dysfunction in patients with psychosis, such as schizophrenia. Both different study design and different psychometric instruments conclude to conflicting results between studies concerning this issue. <sup>18</sup>

In Greece, research into the study of antipsychotic-induced sexual dysfunction is not sufficient. Therefore, few question-naires about sexual side effects related to antipsychotics have been used. In addition, even some of the validated questionnaires do not cover all phases of sexual functioning (sexual desire, sexual arousal, orgasm, resolution), resulting in insufficient information being provided. The aim of the present study was to translate and examine the validity of the Antipsychotics and Sexual Functioning Questionnaire (ASFQ) in a Greek population of psychotic patients.

# MATERIALS AND METHODS

# **Assessment Scale**

The ASFQ contains seven items for men and nine for women on sexual functioning. More specifically, it includes items about sexual desire (libido), orgasm, erection dysfunction, ejaculatory dysfunction, vaginal lubrication, and pain during intercourse (dyspareunia). It also includes items about amenorrhoea, dysmenorrhoea, galactorrhoea, and gynaecomastia. In order to ensure consistency in the structure of the ASFQ, each item is scored as 0 (unknown), 1 (significantly decreased), 2 (mildly decreased), 3 (unchanged), 4 (mildly increased), and finally, 5 (significantly increased).

The questionnaire can be used by both clinicians and researchers to evaluate changes in all stages of sexual function. The assessment takes, on average, 10 minutes. This is an advantage for both mental health professionals and patients suffering from psychosis, as many of them have cognitive deficits and difficulty in concentrating. <sup>19</sup>

The ASFQ is a questionnaire, which is completed during a semi-structured interview and is used to assess sexual function in

patients receiving antipsychotics. The ASFQ guides researchers in introducing the topic in a nondirective and easily understandable way. At the beginning of the interview, the basic clinical and demographic data of the patients are recorded. After a general introduction, the questions related to antipsychotic treatment are structured. Specifically, any previous antipsychotic treatment, the duration of previous antipsychotic treatment, the main reason for quitting previous antipsychotic treatment, the current antipsychotic treatment (antipsychotic and co-medication, including dosage), the experienced result/ results of the treatment with the current medication treatment, as well as, the side effects mentioned spontaneously by the patient are recorded. Next, the questions about sexual function and its possible changes are structured to include a period of 4-6 weeks before the time of the interview. Thus, the time frame of interest of the interview is the past month. 19,20

# Procedure of Translation and Cross-Cultural Adaptation of The ASFQ

The following steps were applied for the translation and cross-cultural adaptation of the ASFQ: (1) procedure preparation, (2) translation of the original source language ASFQ questionnaire into Greek (forward translation), (3) translation of the translated Greek ASFQ questionnaire into the original source language (backward translation), (4) a pilot study in a sample of patients receiving antipsychotics, and (5) review and finalization of the translation and cross-cultural adaptation process of the ASFQ.

During the preparation, it was verified that the original source language ASFQ questionnaire had not been translated into Greek before and the written permission of the source language ASFQ developers was obtained. This was followed by the translation of the ASFQ into Greek by 2 independent bilingual translators with a high level of language proficiency in both languages, who reside permanently in Greece and whose native language is Greek. Each translator produced an independent forward translation of the ASFQ from the original source language to Greek. Subsequently, discrepancies between the independent translations were reconciled and the final form of the translated ASFQ questionnaire into Greek was produced.

During the translation of the already translated Greek ASFQ questionnaire into the original source language ASFQ questionnaire (backward translation), a bilingual translator, who resides permanently in Greece and his native language is Greek, rendered the final form of the ASFQ questionnaire translated into Greek, which had derived from the "forward translation." This was followed by a comparison of the "backward translation" and the original source language ASFQ questionnaire, in order to confirm semantic equivalence and to point out any kind of inaccuracy. Subsequently, the review committee examined the process of the translation and cross-cultural adaptation that took place and identified it as the final version of the ASFQ questionnaire in Greek.

In the next step, a pilot study was conducted with 15 participants in order to ensure that the target audience understood the questions and that the questions are culturally appropriate. Finally, the evaluation and completion of the process included the use of the pilot study data, to ensure that the questionnaire translated into Greek is ready to be distributed to subsequent studies.

# Pilot Study

Study population in the pilot study consisted of 15 outpatients with a diagnosis of schizophrenia or bipolar disorder, who visited the University Psychiatric Clinic of the General Hospital of Athens or the Community Mental Health Center. Convenience sampling was applied due to the difficulty of finding a large number of patients willing to participate in a study concerning their sexual activities.

Inclusion criteria for patients to this methodological study were: (1) being between the ages of 18 and 50 years, (2) clinical diagnosis of schizophrenia or bipolar disorder according to the ICD-10 criteria, (3) oral and/or long-acting injectable antipsychotic treatment, (4) ability to understand and communicate fluently in Greek, (5) ability to participate in the study, depending on the organic and psychological state and (6) informed written consent to participate in the study.

Exclusion criteria for patients in this study were: (1) currently taking general medication, except for antidepressants, which are known to cause sexual dysfunction at a frequency which is greater than 10%, as shown in their package leaflet, (2) pre-existing diagnosis/intervention documented to induce sexual dysfunction, (3) alcohol abuse, (4) inability to give informed consent, and (5) women in pregnancy or lactation.

Patients also completed the "Subjects' Response to Antipsychotics (SRA)" Questionnaire in order to evaluate the validity of the ASFQ. The SRA is a 74-item self-report instrument which assesses patients' responses to antipsychotic medication. The SRA questionnaire was developed to indicate the evaluation of the medication treatment from a broader perspective. Being developed from the patient's perspective, it helps both the patient and the physician to appraise desired and undesired effects of the medication. It includes 8 subscales and answers are scored on a three-point scale: 0 (no), 1 (yes, to a certain degree), 2 (yes, to a high degree). The SRA questionnaire is a valid and reliable instrument, more specifically it has been validated in psychotic patients. The questionnaire is useful in clinical practice, as it can help to systematically monitor and adjust treatment with antipsychotic medication. Completing the SRA questionnaire takes 15-20 minutes. 19-22

The SRA includes 5 questions related to sexual activity: (1) I have more need for sex (item 38), (2) I have my periods less frequently (item 74), (3) I have less need for sex (item 17), (4) it's more difficult to have an orgasm (item 55) and (5) I have too little feeling for sex (item 70). The last 3

questions create the scale of sexual anhedonia, while the second question concerns only women. 19-22 Validity of the ASFQ was calculated by comparing the ASFQ with the corresponding items of the SRA.

Thus, patients completed the ASFQ and SRA questionnaires twice in two weeks. The first administration of the questionnaires took place during the period 1–10 November 2018 and the second 15–25 November 2018.

# **Ethical Approval**

The study was conducted with respect to the protection of participants' rights, such as autonomy/self-disposition, privacy, anonymity-confidentiality, fair care, protection against harm, risk/benefit balance and informed consent. Specifically, the patients who recruited to this study signed an informed consent. In addition, the written permission to conduct the study was obtained from the Scientific Council of the Hospital, that outpatients visited. Ethical approval for the study was provided by the Human Rights and Ethics Committee of the Department of Nursing of the Athens, Greece (Athens, No. Prot. 170).

# Statistical Analysis

IBM SPSS, V.21.0 (IBM Corp. IBM SPSS Statistics for Windows, Version 21.0. Armonk, New York, USA: IBM Corp, 2012) was used to perform statistical analysis. The test-retest reliability of the ASFQ was evaluated using Spearman correlation coefficients by comparing the scores at the test and retest phases. The internal consistency reliability was assessed with Cronbach's alpha coefficient and the validity by comparing responses to ASFQ and SRA. The two-sided level of statistical significance was set to 0.05, so associations with  $P \le .05$  were considered statistically significant.

# **RESULTS**

# Participant Characteristics

The sample population comprised patients, diagnosed with schizophrenia (93.3%) or bipolar disorder (6.7%). The mean age was 42.0 years (SD 10.0), with a range of 25–61 years. The mean duration of the disease was 15 years (SD 6.0). The majority of patients were men (53.3%), single (73.3%) with a secondary level of education (66.7%). Furthermore, most of them were living with others (86.7%) and didn't have a current sexual partner (60%). Detailed demographic and clinical characteristics of the patients in the pilot study are presented in Table 1.

# Test-retest Reliability

The Spearman correlation coefficients in the ASFQ test-retest process are shown in Table 2. In all Likert questions, the Spearman correlation coefficient was 1 (*P*< .001) indicating excellent ASFQ reliability.

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**Table 1.** Demographic and clinical characteristics of the patients in the pilot study

Characteristics		N	%
Gender	Men	8	53.3
	Women	7	46.7
Age (years), mean (SD)		42 (10)	
Marital status	Married Single Divorced/separated, or widowed	3 11 1	20.0 73.3 6.7
Living status	Alone	2	13.3
	With others	13	86.7
Current sexual partner	No	9	60.0
	Yes	6	40.0
Level of education	Primary studies	2	13.3
	Secondary studies	10	66.7
	Higher education	3	20.0
Employment status	Unemployed	12	80.0
	Employed	3	20.0
Smoker tobacco	No	4	26.7
	Yes	11	73.3
Clinical center	Hospital Community Mental Health Center	5 10	33.3 66.7
Diagnosis	Schizophrenia	14	93.3
	Bipolar disorder	1	6.7
Duration of disorder (years), mean (SD)		15 (6)	
Previous hospitalization	No	3	20.0
	Yes	12	80.0
Suicidal attempt	No	13	86.7
	Yes	2	13.3

# Internal Consistency Reliability

The internal consistency of the scale was measured with Cronbach alpha. In more detail, Cronbach's alpha coefficients for ASFQ were 0.90 for men and 0.95 for women in both measurements, indicating excellent ASFQ reliability.

# Validity

The Spearman correlation coefficients between ASFQ and SRA in the first measurement are shown in Table 3. All correlation coefficients between SRA and ASFQ sexual dysfunction questions were moderately positive to strongly positive (between 0.25 and 1), indicating moderate to high validity of ASFQ. The same result was obtained for the correlation between the question "I have my periods less frequently" (item 74) in the SRA and the questions of sexual dysfunction in the ASFQ with the correlation coefficients having higher values (between 0.7 and 0.9). The results are similar to the question "I have more need for sex" (item 38) in the SRA with the correlation coefficients being negative this time. Negative correlations were expected, due to the reverse meaning of the instrument "SRA", which shows that the higher the ASFQ levels the lower the SRA levels and vice-versa. The values are the same in the second measurement (Table 4), which indicates that the ASFQ has excellent validity.

# DISCUSSION

The side effects of antipsychotics can be evaluated by several psychometric instruments, some of them are more specific, as they assess sexual side effects only, whereas others assess multidomain side effects. According to a meta-analysis, of the sexual dysfunction scales, the ASFQ and the Nagoya Sexual Functioning Questionnaire had the best psychometric properties (Cronbach's a >0.70; intrarater and inter-rater reliability approximately 0.70). This finding indicates that there is a discrepancy among the scales used most, such as the Arizona Sexual Scale, and the validated scales.<sup>23</sup> Furthermore, De Boer et al. concluded that the ASFQ, the Changes in Sexual Functioning Questionnaire-14 and the Psychotropic-Related Sexual Dysfunction Questionnaire (PRSexDQ) cover all stages of sexual functioning, hence they should be preferred.<sup>24</sup>

The development of the ASFQ was based on the Udvalg for Kliniske Undersøgelser (UKU) Side Effect Rating Scale, a semistructured multidomain questionnaire that assesses autonomic,

**Table 2.** The Spearman correlation coefficients in the test-retest process for ASFQ

	Spearman correlation coefficients		
ASFQ	First measurement	Second measurement	
Duration of use of previous antipsychotic medication	]*	]*	
Result/results of treatment with the current antipsychotic medication	]*	]*	
Sexual desire	]*	]*	
Orgasm	]*	]*	
Erection	]*	]*	
Ejaculation	]*	]*	
Lubrication	]*	]*	
Pain during sexual intercourse	NC	NC	
Total sexual dysfunction of men	]*	]*	
Total sexual dysfunction of women	]*	]*	

<sup>\*</sup>P < .001; NC = not calculated due to the small number of participants (n = 1); ASFQ = Antipsychotics and Sexual Functioning Questionnaire.

Table 3. The Spearman correlation coefficients between ASFQ and SRA in the first measurement

Spearman correlation coefficients				
	SRA			
ASFQ	Sexual anhedonia	I have more need for sex	I have my periods less frequently	
Sexual desire	0.48	-0.55	0.7	
Orgasm	0.63*	-0.58*	0.8	
Erection	0.25	-0.3	NA	
Ejaculation	0.69	0.23	NA	
Lubrication	1†	-0.9	0.9	
Pain during sexual intercourse	NC	NC	NC	
Total sexual dysfunction of men	0.43	-0.4	NA	
Total sexual dysfunction of women	0.76	-0.7	0.7	

<sup>\*</sup>P < .05.

Table 4. The Spearman correlation coefficients between ASFQ and SRA in the second measurement

Spearman correlation coefficients				
	SRA			
ASFQ	Sexual anhedonia	I have more need for sex	I have my periods less frequently	
Sexual desire	0.48	-0.55	0.7	
Orgasm	0.63*	<b>-0.58*</b>	8.0	
Erection	0.25	-0.3	NA	
Ejaculation	0.69	0.23	NA	
Lubrication	]†	-0.9	0.9	
Pain during sexual intercourse	NC	NC	NC	
Total sexual dysfunction of men	0.43	-0.4	NA	
Total sexual dysfunction of women	0.76	-0.7	0.7	

<sup>\*</sup>P < .05.

neurological, psychological, and other side aspects of antipsychotics. The items in the UKU concerns changes in sexual desire, erectile dysfunction, ejaculatory dysfunction, orgasmic dysfunction, and changes in vaginal lubrication. The UKU has a time frame of 3 days. The UKU has been used in several studies and it is estimated that it has reliable scorings. However, it was found some disadvantages in its structure, such as the short time frame and the interviewer bias. The ASFQ was developed in order to retain the advantages of the UKU but to minimize the disadvantages. <sup>20</sup>

The pilot study conducted for the assessment of reliability and the validity of the ASFQ at its development recruited 17 patients, who were re-evaluated within a week. It was found that the ASFQ had an acceptable test-retest reliability, good face validity, modest concurrent validity, and good sensitivity to changes in antipsychotic treatment for most items of sexual functioning.<sup>20</sup>

This study described the translation and psychometric testing in terms of reliability, and validity of the Greek version of the ASFQ.

It was found that ASFQ has good psychometric properties as an instrument in measuring sexual function in patients receiving antipsychotic treatment, <sup>18,21</sup> as confirmed in the Greek translation.

The Greek translation of ASFQ was patient friendly, since the questions were simple, understandable and brief. In addition, the average time (10 minutes) required to complete the questionnaire was acceptable and the scaling of the subscales was easily interpreted. Considering the problems in cognitive functioning and concentration experienced by the majority of the patients with psychoses, it seems that the duration of completing the questionnaire is an advantage for both clinicians and patients. In this way, the questionnaire can be a useful tool for assessing sexual function in patients receiving antipsychotics.

The reliability of the questionnaire was evaluated through the test-retest process and internal consistency. In both measurements, the Spearman correlation coefficients in all Likert-type questions found a strong positive correlation, while Cronbach's alpha coefficients were found to be between 0.90 and 0.94 for both sexes. The results of the present study are in line with the literature data, which confirms the excellent reliability of the ASFO. <sup>19,22</sup>

The validity of the questionnaire was evaluated using the SRA questionnaire. The SRA is an equally valid and reliable questionnaire, which has been validated in several countries and its psychometric properties have been confirmed.<sup>19</sup> The correlation

<sup>†</sup>P < .001; NC: not calculated due to the small number of people (n = 1); NA: not applicable to men; ASFQ = Antipsychotics and Sexual Functioning Questionnaire; SRA = Subjects' Response to Antipsychotics.

 $<sup>^{\</sup>dagger}P$  < .001; NC: not calculated due to the small number of people (n = 1); NA: not applicable to men; ASFQ= Antipsychotics and Sexual Functioning Questionnaire; SRA= Subjects' Response to Antipsychotics.

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between sexual dysfunction in the SRA and sexual dysfunction questions in the ASFQ was found to be moderately positive to strongly positive in both measurements. Similar studies confirm this positive correlation.<sup>19</sup>

The authors identified several factors that can limit the generalization of the results of the present study. The main limitations are the type of study and the sampling technique. The study was cross-sectional descriptive and nonrandom sampling was performed. By applying the nonrandom selection of participants, samples of convenience are obtained, and as a result, it is not possible to generalize the results of the study to the population from which the sample comes. Furthermore, the sample came from a single Hospital and its Community Mental Health Center so they may reflect the antipsychotic medication "culture" of the staff, as well as a certain community population. An additional limitation of the study is the lack of assessment of the severity of patients' psychotic symptoms. Although the duration of the treatment varies, among patients, this does not been included in the factors that affect the prevalence of sexual dysfunction. 5,25

Finally, a very serious threat to the validity of the study is the small sample size. It should be mentioned that the study was conducted on 15 participants with only 6 having current sexual partners.

In conclusion, the Greek translation of ASFQ is distinguished by exceptional reliability and validity. It is an easy-to-understand questionnaire that does not take much time to complete. The ASFQ questionnaire could be used in clinical trials and daily clinical practice in Greece.

# CONCLUSIONS

This is the first time that the ASFQ is validated in the Greek population. The Greek version of ASFQ warrants its use in the assessment of sexual dysfunction in patients receiving antipsychotic treatment. The ASFQ is useful in evaluating the sexual side effects experienced by patients diagnosed with schizophrenia or bipolar disorder. This questionnaire may identify the severity of sexual dysfunction associated with antipsychotic agents and determine the factors that affect sexual function. In this way, effective interventions for sexual disturbances are more feasible.

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#### STATEMENT OF AUTHORSHIP

Maria Angelaki: Conception and Design, Acquisition of Data, Drafting the Article, Revising It for Intellectual Content, Final Approval of the Completed Article; Giorgos Alevizopoulos: Conception and Design, Drafting the Article, Revising It for Intellectual Content; Petros Galanis: Analysis and Interpretation of Data, Drafting the Article, Revising It for Intellectual Content, Final Approval of the Completed Article; Artemis Igoumenou: Drafting the Article, Revising It for Intellectual Content, Final Approval of the Completed Article; Eirini Alexiou: Drafting the Article, Revising It for Intellectual Content, Final Approval of the Completed Article.

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