SEXUAL DYSFUNCTION INDUCED BY ANTI-PSYCHOTICS AND ANTI-DEPRESSANTS IN DRUG NAIVE PATIENTS – A COMPARATIVE STUDY

M. Mohanalakshmi[1], W. J. Alexander Gnana Durai[2], B. Kalaimathi[3], Nileena N. K. M[4], D. Punithavathi[5], K. Gayathri[6], Saravana Jothi R[7]

[1]Assistant Professor, Department of Pharmacology, Stanley Medical College, Chennai.
[2]Professor and HOD, Department of Psychiatry, Stanley Medical College, Chennai.
[3]Assistant Professor, Department of Pharmacology, Stanley Medical College, Chennai.
[4]Junior Resident, Department of Psychiatry, Stanley Medical College, Chennai.
[5]Junior Resident, Department of Psychiatry, Stanley Medical College, Chennai.
[6]Junior Resident, Department of Psychiatry, Stanley Medical College, Chennai.
[7]Associate Professor, Department of Psychiatry, Stanley Medical College, Chennai.

ABSTRACT

BACKGROUND

The aim of this study was to determine and compare sexual dysfunction caused by anti-psychotics and anti-depressants in drug naïve patients.

MATERIALS AND METHODS

Patients diagnosed as drug naïve schizophrenic and depression as per DSM-5 criteria & age between 18-45 years were recruited and allocated into group A (n=30)–receiving anti-psychotics & group B (n=30) receiving anti-depressants after informed consent by the patients. Sexual dysfunction was assessed by Arizona Sexual Experiences Scale (ASEX) during the initial 2 months of therapy.

RESULTS

ASEX mean for patients receiving antipsychotics increased from the baseline of 7.97 to 17.23 and the ASEX mean for patients receiving antidepressants increased from baseline of 7.80 to 18.67 with p value of 0.249 which is not statistically significant. Among the antipsychotics haloperidol ASEX mean increased from 7.87 to 18.00 and risperidone mean increased from 8.07 to 16.47 with the p value of 0.335 which is not significant. More patients on haloperidol showed evidence of sexual dysfunction as assessed by ASEX scoring than risperidone though p value was not significant. Among the two antidepressants ASEX score mean for amitriptyline patients increased from 8.07 to 16.47, and that of fluoxetine from 7.53 to 16.47 with the p value of 0.018* statistically significant at α of 0.05 level.

CONCLUSION

This study shows presence of sexual dysfunction in patients receiving antipsychotics & antidepressants by 2nd month of therapy though statistically not significant. Fluoxetine group patients developed statistically significant sexual dysfunction. Implications for future research about sexual dysfunction in all new treatments should be strongly taken into account because this side effect adds to the emotional stress and worsening of mental dysfunction.

KEYWORDS

ASEX Score, Mental Illness Therapy, Sexual Dysfunction.

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BACKGROUND

Human relationships often require acceptable levels of sexual expression which is essential to provide a sense of psychological, physical and social well being. Clinical and epidemiological studies reveal that schizophrenia and depression are correlated with deterioration of sexual function and satisfaction, even in untreated patients.[1] Most antidepressant and antipsychotic drugs have sexual side effects but it is tough to establish precisely the incidence of dysfunction arising from treatment. Spontaneous reporting of sexual side effects by the patient is very less Not only psychiatric symptoms reduce sexual functioning but also other drug related adverse effects such as sedation, extrapyramidal effects and weight gain. can also reduce sexual desire. Psychotropic drugs can interfere with any stage of sexual response cycle viz. desire, erection/ lubrication, orgasm and ejaculation. Men often report

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Corresponding Author:
Dr. M. Mohanalakshmi,
Assistant Professor,
Department of Pharmacology,
Stanley Medical College, Chennai-1.
E-mail: drmohanalakshmi@gmail.com
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erectile problem and women report decreased desire.[2] So reliable detection is possible only with methodical analysis made at baseline and during treatment.

Sexual Dysfunction in Depression

Recent studies reveal that there is an increased prevalence of sexual dysfunction in major depression, as high as 70%.[3] most commonly presenting as a lack of libido. However with treatment of depression, sexual desire is found to improve. Paradoxically, successful antidepressant treatment by itself can cause other detrimental effects on sexual function. Sexual dysfunction may additionally stem from relationship problems, comorbid alcohol abuse physical illness, inadequate treatment of depression or a combination of these factors. Antidepressants are found to cause increased arousal dysfunction in women whereas in men, they are found to produce increased rates of orgasm and desire dysfunction. Sexual dysfunction related to antidepressants are found to be dose-dependent.[4]

Prevalence of sexual dysfunction due to antidepressants reported in clinical studies vary based on the evaluation modus. More cases were identified by studies which used instruments (questionnaires) to gauge sexual dysfunction than those that relied merely on spontaneous reports (both in clinical trials and pharmacovigilance agencies such as CARM).[5] and it is mainly due to patients avoid discussion of their sexual problems with their treating doctor and stop using the drug without notice.

According to reports of a meta-analytic study, it was found that 80% of patients receiving antidepressants were shown to exhibit sexual dysfunction, following treatment.[5] Sertraline, paroxetine, citalopram and venlafaxine were shown to exhibit the greatest risk in the meta-analysis. Moclobemide, bupropion and mirtazapine showed no difference from placebo. Intermediate effect was seen in antidepressants such as imipramine and escitalopram.

The multifactorial aetiology of antidepressant associated sexual dysfunction leads to difficulty in its management. Hence it is essential to confirm and assess any existing sexual dysfunction before commencement of treatment and the possible cause. While selecting an antidepressant, it is important to discuss with the patient the possibility of sexual dysfunction emerging with treatment. Questions regarding sexual dysfunction in patients receiving antidepressants are to be put forward delicately as they are disinclined to discuss their sexual dysfunction with their doctor. Upon broaching the issue however, doctors are often surprised by the relief in the patients and their willingness to discuss their sexual function. Close supervision of sexual dysfunction during treatment aids to increase the quality of life and augment adherence to treatment. Patients are reassured when they come to know how common the problem is and how it is often manageable.

Sexual Dysfunction in Schizophrenia

Of all the side effects of antipsychotics, one of the most distressful and one that has been rated as causing a marked decrease in quality of life in patients is sexual dysfunction. When compared to the general population or those patients with any other psychiatric disorders, sexual dysfunction rates has been seen to be higher in schizophrenic patients.[6] A positive correlation has been found to exist between the reported severity of sexual dysfunction and the severity of psychotic symptoms.

Of the antipsychotics, the two with reportedly highest association with risk of sexual dysfunction are risperidone and haloperidol. These drugs are commonly associated with menstrual irregularities, decreased vaginal lubrication and amenorrhea in women and ejaculatory and erectile dysfunction in men. They may additionally cause general effects that reduce the libido and orgasm.[7]

With the exception of ejaculatory and erectile problem, clozapine has been reported, in previous studies on antipsychotics and their associated side effects, as having lower rates of sexual dysfunction. Quetiaptine was found to exhibit a lower effect on sexual function with respect to the number of affected patients and dysfunction severity.[8] Aripiprazole was found to have the least risk of sexual dysfunction, based on current evidence. More research is needed in this area.[9] Sexual dysfunction is shown to be associated with a negative attitude towards treatment and often causes non-adherence.[10]

Neurotransmitters and Sexual Function

Normal sexual function is maintained by the actions of many hormones and neurotransmitters, though their exact actions are not entirely understood.

They include dopamine, noradrenaline, serotonin (5-hydroxytryptamine; 5-HT), acetylcholine, γ-aminobutyric acid, oxytocin, nitric oxide, arg-vasopressin, angiotensin II, gonadotrophin releasing hormone, substance P, neuropeptide Y and cholecystokinin. Of these, dopamine, nitric oxide and serotonin possibly have the most important roles in the pathophysiology and sexual dysfunction arising from antidepressant and antipsychotic drugs.[11]

Treatment-emergent sexual problems have been described as 'the unspoken side effect of antipsychotics' and physicians underestimate the sexual and menstrual adverse effects of antipsychotic drugs. Hence a two month follow-up study on sexual dysfunctions induced by customarily prescribed anti-psychotics and anti-depressants in drug naïve patients was conducted to assess the magnitude of this under-reported problem in Indian population.

AIM

To compare the sexual side effects induced by antipsychotics and those produced by antidepressants in drug naïve patients.

MATERIALS AND METHODS

Design- Prospective, Comparative, Open labeled, Parallel grouped Study.

Inclusion Criteria

- Patients diagnosed as drug naïve schizophrenic and depression as per DSM IV-TR criteria.
- Patients in the age group of 18-45 years.

Exclusion Criteria

- Patients already exposed to antipsychotic drugs or anti-depressants,
- Patients with known drug hypersensitive reactions,
- Patients with renal & liver disorders,
- Patients in whom risperidone, haloperidol, amitriptyline, fluoxetine were contra-indicated,
- Patients with established sexual dysfunction assessed by baseline questionnaire,
- Patients who are not willing to give informed consent were excluded.

Tools used for the Study

A proforma for sociodemographic details, DSM IV–TR criteria for schizophrenia and depression and ASEX scale.

Arizona Sexual Experience Scale (ASEX).[12]

ASEX is a user-friendly 5-item rating scale that helps in quantifying sex drive, arousal, vaginal lubrication/penile erection, ability to reach orgasm, and satisfaction from orgasm. Each item can be scored from 1- 6 based on the severity. Hence the total score can range from 5-30, higher scores indicating more sexual dysfunction.

Primary Outcome

Detection of sexual side effects within two months of starting anti-psychotics or anti-depressants in drug naïve psychiatric disorder patients by comparing baseline ASEX score with fortnight Asex score for two months.

After getting the informed consent patients were allocated into the following groups.

Group A- Patients receiving anti-psychotics--risperidone 4-6 mg (or) haloperidol 5-10 mg.

Group B- Patients receiving anti-depressants--fluoxetine 20-40 mg (or) amitriptyline 25-50 mg.

As per psychiatrist decision schizophrenic patients were started on either risperidone or haloperidol and the depressive patients were started on either amitriptyline or fluoxetine. One week after initiation of therapy patients sexual performance was assessed by using ASEX scale.[12] for computing the baseline score.

Patients were reviewed during their follow up in OPD every 15 days and ASEX score were assessed to detect presence of sexual abnormality.

Statistical Data Analysis

Statistical data analysis was using Group statistics & Independent T Test.

RESULTS

	Antipsychotics Group (Haloperidol and Risperidone)	**Antidepressants Group (Amitriptyline and Fluoxetine)**
	Number and Percentage	**Number and Percentage**
Education Status		
Uneducated	6 (20)	2 (6.6)
Primary school	10 (33.3)	15 (50)
High school	9 (30)	10 (33.3)
Degree	5 (16.6)	3 (10)
Occupation Status		
Student	0	0
Unemployed	20 (66.6)	14 (13.3)
Self employed	10 (33.3)	16 (53.3)
Socioeconomic Status		
Low	20 (66.6)	13 (43.3)
Lower middle	6 (20)	10 (33.3)
Upper middle	4 (13.3)	7 (23.3)
Family H/O Mental Illness		
Yes	11 (36.6)	6 (20)
No	19 (63.3)	24 (80)

Table 1. Sociodemographic Profile

Newly diagnosed cases of schizophrenia treated either with risperidone or haloperidol and new cases of depression treated with either amitriptyline or fluoxetine were included in this study spanned for a period of 6 months. 30 patients in both the groups had completed follow up to assess sexual dysfunction.

After the initial phase of treatment, patients were screened for presence sexual dysfunction by ASEX questionnaire explained in native language by the principle investigator and the treating psychiatrist. Patients queries were clarified and ASEX scoring done. Partners were also separately questioned for presence of any pre existing sexual dysfunction. Those with normal sexual history were followed up every 2 weeks for first month and 3rd scoring done at the end of 2 months of therapy. Patients were reviewed with partner during follow up period.

ASEX mean for patients receiving antipsychotics increased from the baseline of 7.97 to 17.23 and the ASEX mean for patients receiving antidepressants increased from baseline of 7.80 to 18.67 with p value of 0.249, which is not statistically significant.

Among the antipsychotics haloperidol ASEX mean increased from 7.87 to 18.00 and risperidone mean increased from 8.07 to 16.47 with the p value of 0.335 (not significant). More patients on haloperidol showed evidence

of sexual dysfunction as assessed by ASEX scoring than risperidone though p value was not significant.

Among the two antidepressants ASEX score mean for amitriptyline patients increased from 8.07 to 16.47, and that of fluoxetine from 7.53 to 16.47 with the p value of 0.018* statistically significant with an αof 0.05 level.

	Group	N	Mean	Std. Deviation	Std. Error Mean	p value
2nd wk	Anti-Psychotics	30	7.97	1.921	.351	0.739
	Anti-Depressants	30	7.80	1.937	.354	
4th wk	Anti-Psychotics	30	12.60	2.541	.464	0.458
	Anti-Depressants	30	12.10	2.644	.483	
6th wk	Anti-Psychotics	30	14.90	3.763	.687	0.111
	Anti-Depressants	30	16.57	4.191	.765	
8th wk	Anti-Psychotics	30	17.23	4.281	.782	0.249
	Anti-Depressants	30	18.67	5.215	.952	

Table 2. Group Statistics

	Sub Group	N	Mean	Std. Deviation	Std. Error Mean	p value
2nd wk	Haloperidol	15	7.87	1.885	.487	0.781
	Risperidone	15	8.07	2.017	.521	
4th wk	Haloperidol	15	11.80	2.042	.527	0.084
	Risperidone	15	13.40	2.798	.722	
6th wk	Haloperidol	15	14.73	4.131	1.067	0.813
	Risperidone	15	15.07	3.494	.902	
8th wk	Haloperidol	15	18.00	4.259	1.100	0.335
	Risperidone	15	16.47	4.307	1.112	

Table 3. Group Statistics

	Sub Group	N	Mean	Std. Deviation	Std. Error Mean	p value
2nd wk	Amitriptyline	15	8.07	2.017	.521	0.461
	Fluoxetine	15	7.53	1.885	.487	
4th wk	Amitriptyline	15	13.07	2.658	.686	0.043
	Fluoxetine	15	11.13	2.326	.601	
6th wk	Amitriptyline	15	15.13	3.720	.960	0.060
	Fluoxetine	15	18.00	4.259	1.100	
8th wk	Amitriptyline	15	16.47	4.307	1.112	0.018
	Fluoxetine	15	20.87	5.235	1.352	

Table 4

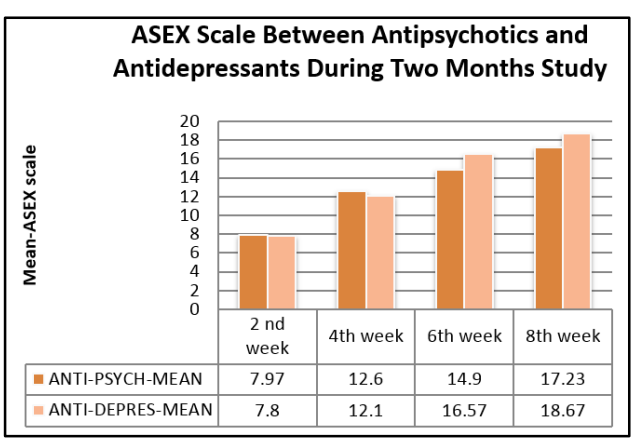

Figure 1. ASEX Scale Between Antipsychotics and Antidepressants During Two Months Study

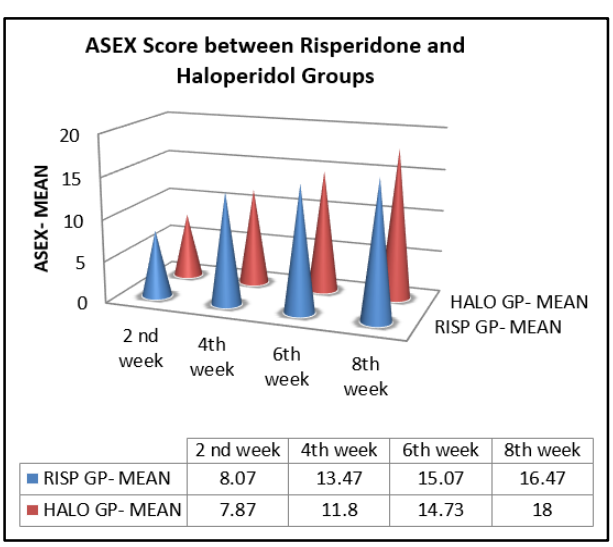

Figure 2. ASEX Score between Risperidone and Haloperidol Groups

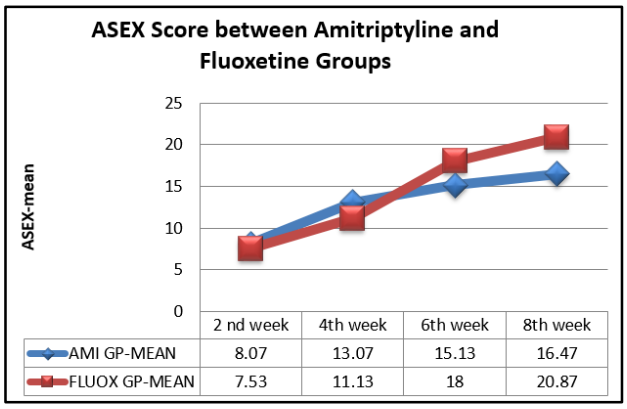

Figure 3. ASEX Score between Amitriptyline and Fluoxetine Groups

DISCUSSION

All patients enrolled for the study receiving either haloperidol or risperidone and either amitriptyline or fluoxetine showed evidence of sexual dysfunction at the end of 2 weeks of therapy. 3 patients in antipsychotics group & 2 patients in antidepressants group showed moderate affection at the end of 2 weeks of therapy.

The typical antipsychotic haloperidol raises serum prolactin levels to 20~40 ng/ml even on therapeutic dose.[13] From evidence of a large prospective cohort study, 71.1% of women and men who took haloperidol for more than 12 months complained of sexual dysfunction depending on the modified version of the Udvalg for Kliniske Undersøgelser (Danish for dysfunction Clinical Examinations'; UKU Side Effect Rating Scale).[14] Risperidone though the prototype of atypical antipsychotics, has increased probability of increasing prolactin levels. According to many cross sectional studies and clinical trials, risperidone at therapeutic doses is found to increase serum prolactin level upto 30- 60 ng/ml in a dose dependant manner. Of the atypical antipsychotics, risperidone was reported to cause elevation of prolactin levels in a prospective 5 year observational study. Reports of a large prospective observational study showed 67.8% of the women and men who received risperidone for more than a year experienced side effects of sexual dysfunction.[15,16,17]

A study by Kuyoung Lee in 2010 about antidepressants induced sexual side effects among newer antidepressants in a naturalistic settings showed 46.2% of sexual dysfunction in fluoxetine receiving patients.[18]

The approximate prevalence of sexual dysfunction with tricyclic antidepressants is about 30%. These side effects can probably be best explained by the anticholinergic properties of tricyclic antidepressants, with the one exception of reduced libido where their dopamine antagonist properties are likely to be involved. Tricyclics also produce serotonin re-uptake inhibition to some extent. There appears to be some correlation between this and their propensity to cause sexual dysfunction. The tricyclic antidepressants are a diverse group of compounds whose lack of receptor selectivity indicated a possible combination of neurotransmitter systems are likely to be involved in the production of their sexual side effects.[19,20]

In our study, among the two antipsychotics 4 female patients and 2 male patients in haloperidol group, totally 20% showed ASEX score between 17-25 indicating severe dysfunction. 5 female patients, 4 male patients in risperidone group, totally 30% found have severe dysfunction.

Among the antidepressants 6 male patients & 4 female patients, totally 33.33% were moderately affected (ASEX score 9-16) and 5 patients (16.66%) were severely affected. In the fluoxetine group 7 male patients &3 female patients were severely affected (33.33%) and 4 female patients (13.33%) were moderately affected.

The mechanism of SSRI and SNRI induced sexual dysfunction is thought to involve indiscriminate stimulation of post synaptic 5HT-2a and 5HT-2c receptors by the increased synaptic levels of serotonin. Gender, race and duration of treatment do not appear to predict sexual dysfunction. However, prior history of antidepressant-induced sexual dysfunction increases the risk of developing it again.

It is essential for the clinician to enquire as a routine regarding sexual symptoms before the prescription of antipsychotics and upon follow-up. Antipsychotics with lesser effects on prolactin levels may be found to cause less sexual dysfunction, especially in women, and hence these drugs are to be preferred to prevent sexual problems.

The management of sexual dysfunction associated with antidepressants include reducing the dose of antidepressants, drug holidays, switch to another class of antidepressants, continuing treatment as wait and watch and addition of reversal agents (phosphodiesterase inhibitors). But these options have their own disadvantages. The dose reduction of antidepressants may increase the relapse of illness.[21] Drug holidays may affect the drug compliance, emergence of withdrawal symptoms with antidepressants of short halflife.[22,23] By switching to another class of antidepressants, risk of relapse will increase and emergence of new side effects. By continuing the same treatment as wait and watch will take several months for resolution of symptoms. The addition of reversal agents like phosphodiesterase inhibitors will have addition side effects of it. Antidepressant associated sexual dysfunction is generally reversible on discontinuation of treatment.

The treatment options for reducing the sexual dysfunction associated with antipsychotics are reducing the dose of antipsychotics, switching to another class of antipsychotics or with different mechanism, augmentation of treatment or addition of reversal agents like dopamine agonists.[6,8] But these have their own disadvantages. The dose reduction of antipsychotics may increase the risk of relapse. The switching to different antipsychotics may increase the risk of relapse and emergence of new side effects. The addition of reversal agents like dopamine agonists may aggravate the psychosis and emergence of new side effects.

Other factors contributing to sexual dysfunction include the disease itself, psychosocial factors (including performance anxiety), comorbid diseases (especially cardiovascular) and concomitant medication.[8]

LIMITATIONS OF THE STUDY

Indian population are generally reluctant to disclose sexual dysfunction. They generally attribute to emotional, economic, environmental factors. In this study only antipsychotics and antidepressants therapy is taken into account to assess appearance or worsening of sexual dysfunction. Contribution of both disease progression and therapy towards sexual dysfunction could not be discriminated in this study. Stratified randomization and considering sexual dysfunction in each gender separately has not been done. Other co-morbid factors which can aggravate or cause sexual dysfunction are not documented in this study. More studies on the effects of antidepressant and antipsychotic drugs on sexual function are needed.

CONCLUSION

This study shows presence of sexual dysfunction in in patients receiving antipsychotics & antidepressants by 2nd month of therapy though statistically not significant. Fluoxetine group patients developed statistically significant sexual dysfunction compared to amitriptyline. Implications for future research about sexual dysfunction in all new treatments should be strongly taken into account because this side effects adds to the emotional stress and worsening of mental dysfunction and for better compliance and prognosis.

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