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ASSESSMENT OF PREVALENCE OF SEXUAL SIDE EFFECTS IN PSYCHIATRIC PATIENTS RECEIVING PSYCHOTROPIC DRUGS AND THE QUALITY OF LIFE ASSESSMENT IN TERMS OF SEXUAL SATISFACTION-A PILOT STUDY

SHAN SASIDHARAN[1], P. N SURESH KUMAR[2], ANIL BABU[3], B. SEETHADEVI[4] & R. RAJU[5]

[1,3,4,5]Department of Pharmacy Practice, National College of Pharmacy, Calicut, Kerala, India

[2]Department of Psychiatry and Behavioral Medicine, KMCT Medical College, Calicut, Kerala, India

ABSTRACT

Sexual satisfaction is one of the major determinant of quality of life. Our main objective of this study is to assess the prevalence of sexual dysfunction in patients receiving Psychotropic drugs, to assess the category of psychiatric diseases more prone to sexual dysfunction and to assess class of psychotropic drugs produces sexual side effects frequently. The study is Open, naturalistic, cross sectional, observational for 6 months in a tertiary care teaching hospital. The data collection was done only once at a single point of time during the study. The data are collected by the use of standard validated questionnaire like DISF (Derogates Interview for Sexual function) male and female translated version duly permitted from the author. And the dates were statistically analysed and evaluated. Thus obtained results were promising for further studies. In male and female patients using psychotropic drugs a significantly higher incidence of sexual dysfunction was observed as ADR. In male and female patients using psychotropic drugs, the quality of life in terms of sexual function was significantly lower by comparing age, sex, marital status matched control group. Antidepressants showed significantly higher incidence of sexual dysfunction in both male and female psychiatry patients followed by antipsychotics and then anxiolytics.

KEYWORDS: Sexual Dysfunction, Anti Depressants, Psychotropic Drugs, DISF, Sexual Satisfaction

INTRODUCTION

Sexual satisfaction is the one of the most important determinant of general quality of life of all human being. In psychiatric patients the level of this determinant is varying significantly as they are consuming the drugs which may alter and provoke the general balance of neurotransmitters and hormones which play a vital role in ultimate successful sexual act and satisfaction. It is proved from various studies in around the globe that the major drugs are belonging to the category of antipsychotics and antidepressants which is causing sexual dysfunction in male and female psychiatric patients. The degree of severity of sexual dysfunction varies depending psychopathological and pharmacotherapeutical factors like category of psychiatric drugs, dose, and duration of treatment.[1, 3, 9] Psychotropic drugs are the group of medicines to treat, manage and alleviate the symptoms of different psychiatric and neuropsychiatric conditions. As much as these medicines are well known for its therapeutic effects that much it has various grades of ADRs (minor, to major including death) .[2,3,5,7] The quality of life of psychiatric patients becoming worsen due to unpleasant side effects of theses medication. Antidepressants and antipsychotics are in first category drugs which had an ADR profile of sexual dysfunction in various levels viz Stimulation, interest, erection ,sex drive and orgasm. Different studies done worldwide support the role of antidepressants in the drug induced sexual dysfunction. Tricyclic antidepressants are those categories which has lowest

incidence of sexual dysfunction but venlafaxime has the highest role in the same. Antipsychotics in general have the side effects of sexual dysfunction.[2, 10, 11] Second generation antipsychotics has lesser incidence of sexual side effects than first generation. Rispiridone shows highest incidence in this category. It became very essential to conduct a study on this contest to prove the role of pharmacotherapy in the level of sexual satisfaction in Psychiatric patients.[4,6,8]

OBJECTIVE

- To assess the prevalence of sexual dysfunction in patients receiving Psychotropic drugs.
- To assess the category of psychiatric diseases more prone to sexual dysfunction.
- To assess class of psychotropic drugs produces sexual side effects frequently.

Plan of Work

Study Design

Institutional Ethical Committee duly permitted to carry out the research work. The certificate of approval is attached in appendix.

Study Type: Open, naturalistic, cross sectional, observational.

Study Site: Psychiatry department of tertiary care teaching hospital.

Study Duration: 6 months

Sample Size: Test sample-50, Control - 50

Sample Size Determination Method: Simple random sampling.

Inclusion Criteria

- Should be at least by 18 years old or greater
- Should be a psychiatric patient under a registered psychiatrist and should be taking psychotropic drugs at least for a minimum period of last 3 months as test group and should be healthy volunteer as control group.
- Should be willing to give a written informed consent form and should understand and agree the terms and conditions mentioned in the informed consent form.

Exclusion Criteria

- Should not be a pregnant lady
- Should not underwent any surgeries in genitourinary system.
- Should not have any co-morbidity which can cause sexual dysfunction other than psychiatric diseases.
- Should not be a substance abuser
- Should not have a prior history of sexual dysfunction
- Patients taking other medication which has an established adverse drug reaction as sexual dysfunction other than psychotropic drugs.

- Should not be priest/saint/nuns socially isolated persons.

METHODOLOGY

Phase 1

- Obtained the IEC/IRB approval for the study.
- Detailed literature review.
- Procured the scales/ questionnaires /statistical tools/ software.
- Study sample determination/ selection of subjects / collection Informed consent form from subjects.

Phase 2

- Data collection by using questionnaires and validated scales.
- Compiling the data.

Phase 3

- Analysis of reports by using various statistical tools.
- Documentation and presentation.

SELECTION OF SUBJECTS FOR STUDY

Test Selection

By analysing inclusion exclusion criteria I selected the patients for study with the supervision of clinical psychiatrist and informed those subjects/ relatives or caretaker of those subjects regarding the study and given informed consent form for signing and given ample of time for decision making. Once they are making decision in favour of participating in the study the subjects have to sign informed consent form written in Malayalam with date and name. The documented ICF is filed properly and securely.

Control Selection

Controls also selected according to the inclusion exclusion criteria, they should be age / sex/ marital status matching healthy volunteer. The control and test ratio is 1: 1 so each test has individual identical matching control. The informed consent were signed out from each control and documented.

In order to keep privacy of the subject I am providing them unique code number for every subject. The code is a mixture of alphabets and numerical. Alphabets are C and T where C represents Control and T represents test, Numerical involves serial number. For e.g.: C 01indiated control 1 and T 01 indicates test 1.

Data Collection Procedure

As it is a cross sectional study the data collection is done only once at a single point of time during the study. The data are collected by the use of standard validated questionnaire like

DISF (Derogates Interview for Sexual function) male and female translated version. I got the permission from author of the DISF to translate to Malayalam and utilise the translated version for this study.

The permission letter is attached as appendix along with DISF questionnaire male and female version.

The DISF is distributed to tests and control and allowed to read it fully and given time to clarify any doubts, then after the subjects were interviewed and noted their response promptly and calculate the score and documented.

RESULTS

Details of test subjects

Total number of subjects: 50 nos

Total number of Males: 23 nos

Total number of Females: 27 nos

Number of patients using anti-depressants alone: 17

Number of patients using anti-depressants along with other psychopharmacological agents= 18

Number of patients using anti-psychotics:5

Number of patients using anti-anxiety drugs alone: 10

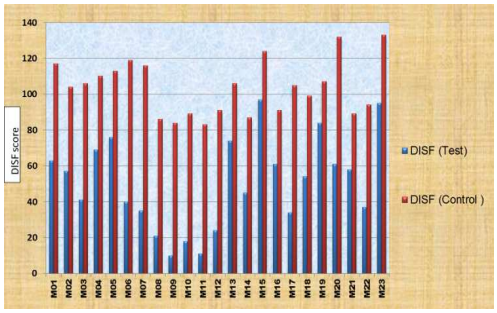

Figure 1: DISF Scores (Male)

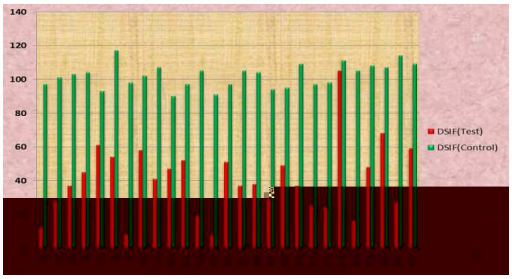

Figure 2: DISF Scores (Female)

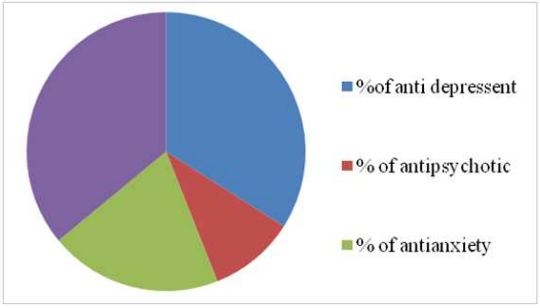

Figure 3: Percentage of Sexual Side Effects by Psychotropic Drugs

A REPORT ON THE STATISTICAL ANALYSIS OF THE DATA

Data collected for the study were compiled and analyzed statistically using student's 't' test for comparison of Test and Control groups and X^2 test for studying the significance of association. Results of the analysis of the data are summarized below.

Table 1: Comparison of Mean Score in Test and Control Groups

Sex	n	Test Group		Control Group		|t|	df	P-Value
		mean	SD	mean	SD			
Male	23	50.65	25.28	103.70	15.14	8.635	44	P<0.001
Female	27	40.11	21.13	102.15	6.94	14.690	52	P<0.001
combined	50	44.96	50.73	102.86	103.49	3.552	98	P<0.001

From the above table it could be inferred that

- The mean test scores of males is significantly lower than that of the control group ($p<0.001$).
- Mean test scores of females is significantly lower than that of the control group ($p<0.001$).
- Mean test scores of the combined group (male & female) is significantly lower than that of the control group. ($p<0.001$).

For studying the association between scores under different groups in test and control, X^2 statistic calculated is 87.000, having degrees of freedom 2. X^2 is very highly significant ($p<0.001$) indicating that significant association exists between the two as it could be evident from the following Table.

Table 2: Distribution of the Members as Score Wise in Test and Control Group

Scores	Test	Control
<40	22	0
40-80	24	0
>80	4	50

DISCUSSIONS

- The control group possess a significantly higher levels of Sexual function compared to test population in male population.
- The control group possess a significantly higher levels of Sexual function compared to test population in female population.
- The control group possess a significantly higher levels of Sexual function compared to test population in a combination of male and female population.
- In male and female patients using psychotropic drugs a significantly higher incidence of sexual dysfunction was observed as ADR.
- In male and female patients using psychotropic drugs, the quality of life in terms of sexual function is significantly lower by comparing age, sex, marital status matched control group.
- Antidepressants shows significantly higher incidence of sexual dysfunction in both male and female psychiatry patients followed by antipsychotics and then anxiolytics.

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CONCLUSIONS

The study we had done is a pilot study which is focusing on the ADRs of Psychotropic drugs especially the sexual side effects and measurement of quality of life in terms of sexual satisfaction . The study were conducted on a small group of study population and found promising results both statistically and scientifically. The mean test scores of males is significantly lower than that of the control group ($p<0.001$).Mean test scores of females is significantly lower than that of the control group ($p<0.001$).Mean test scores of the combined group (male & female) is significantly lower than that of the control group. ($p<0.001$).In male and female patients using psychotropic drugs a significantly higher incidence of sexual dysfunction was observed as ADR. We observed the psychotropics are producing a higher rate of sexual side effects in both male and female patients . Antidepressants shows a significantly higher incidence of sexual side effects in both the sexes followed by anti psychotics and anxiolytics. Quality of life of psychiatric patients on psychotropic drugs was found very poor in terms of sexual satisfaction. So in future we would like to do an elaborative study on a higher sample size.

REFERENCES

1. http://www.nimh.nih.gov/health/publications/mental-health-medications/nimh-mental-health-medications.pdf
2. http://www.cchr.org/sites/default/files/The_Side_Effects_of_Common_Psychiatric_Drugs.pdf
3. http://www.merseycare.nhs.uk/Library/What_we_do/Clinical_Services/Pharmacy/SideEffectsofPsychotropics-Finalv3.pdf
4. Lizza EF, Rosen RC. Definition and classification of erectile dysfunction: report of the Nomenclature Committee of the International Society of Impotence Research. Int J Impot Res. 1999; 11:141.
5. Sachs B, RL M. The physiology of male sexual behavior. In: The Physiology of Reproduction. Edited by E. Knobil, J. Neill, L. Ewing. New York: Raven Press, pp. 1393–1423, 1988
6. Carrier S, Zvara P, Nunes L, et al. Regeneration of nitric oxide synthase-containing nerves after cavernous nerve neurotomy in the rat. J Urol. 1995; 153:1722.
7. Christ GJ, Moreno AP, Parker ME, et al. Intercellular communication through gap junctions: a potential role in pharmaco mechanical coupling and syncytial tissue contraction in vascular smooth muscle isolated from the human corpus cavernosum. Life Sci. 1991; 49:PL195.
8. Lizza EF, Rosen RC. Definition and classification of erectile dysfunction: report of the Nomenclature Committee of the International Society of Impotence Research. Int J Impot Res. 1999; 11:141.

9. Bancroft J. Lecture 4: psychogenic erectile dysfunction-a theoretical approach. Int J Impot Res. 2000; 12 (Suppl 3):S46.

10. Martin-Morales A, Sanchez-Cruz JJ, Saenz de Tejada I, et al. Prevalence and independent risk factors for erectile dysfunction in Spain: results of the Epidemiologia de la Disfuncion Erectil Masculina Study. J Urol. 2001; 166:569.

11. Graham C, Regan J. Blinded clinical trial of testosterone enanthate in impotent men with low or low-normal serum testosterone levels. Int J Impot Res. 1992;P144

12. Bemelmans BL, Meuleman EJ, Anten BW, et al. Penile sensory disorders in erectile dysfunction: results of a comprehensive neuro-urophysiological diagnostic evaluation in 123 patients. J Urol. 1991; 146:777.