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A CLINIC BASED OBSERVATIONAL STUDY ON ADVERSE DRUG REACTIONS IN PSYCHIATRY

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ABSTRACT

Background: Pharmacovigilance in psychiatry units can play vital role in detecting adverse drug reactions and alerting physicians to such events, thereby protecting the user population from avoidable harm. **Objectives:** To study the prevalence and pattern of Adverse drug reactions of various drugs prescribed in the psychiatric clinic. **Methodology**: This was a prospective observational study, carried out at a psychiatric hospital in Telangana region for a period of six months from January 2017 to June 2017. Causality of assessment of ADRs was done based on WHO –UMC causality assessment system, Naranjo's Causality assessment, Modified Hartwig and Siegel scale, Schumock and Thornton scale. **Results:** 500 patients data was collected and 446 ADRs were reported. Most of the ADRs reported were found to be possible and probable type upon assessment using various causality assessment scales. **Conclusion**: This study suggested that a hospital-based monitoring of ADRs by well trained clinical pharmacists is the need of the day for providing an optimum healthcare to the patient.

KEYWORDS: Pharmacovigilance, Adverse drug reactions (ADRs), Psychiatry.

INTRODUCTION

Adverse drug reaction (ADR) is defined as "A noxious, unintended and undesirable effect that occurs as a result of dose normally used in man for diagnosis, prophylaxis and treatment of disease or modification of physiological function.[1] Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems. It includes ADR monitoring as one of the

activities which involves detection and assessment of such adverse effects occuring at therapeutic doses. Psychotropic drugs like antidepressants, antipsychotics and mood stabilizers are associated with adverse effects which can affect the compliance and course of treatment in mental disorders.[2] Many of these adverse effects are probable. Clinician's awareness about the adverse effects of psychotropic drugs and their preventability can foster rational and safe use of these medicines.

METHODOLOGY

This is a prospective observational study, carried out at Jaya Krishna psychiatry care and counseling center, Hanamkonda, Telangana region for a period of six months from January 2017 to June 2017. The study was approved by institutional ethics committee and patient consent was also obtained. Patient prescriptions and case sheets were studied to obtain demographic details, co-morbidities, factors influencing their quality of life and prescribed medications. Questionnaires appropriately designed for additional information were used and data was obtained by interacting with the patients. The adverse events were assessed by using causality assessment scales. Pregnant women and patients less than 10 years of age were excluded from the study.

RESULTS AND DISCUSSION

Table -1: Adverse drug reactions observed in the study population [n=446]

S.NO	Adverse drug reaction	% of patients affected
1.	Weight gain	20
2.	Drowsiness	18
3.	Dizziness	15
4	Anorexia	12
5.	Suicidal ideation	10
6.	Orthostatic hypotension	8
7.	Dystonia	7
8.	Constipation	3
10.	Drymouth	5
11	Sexual dysfunction	2

Table 1 shows that weight gain and drowsiness were the two effects seen in most number of patients as almost all prescription drugs in psychiatry have these two effects as most commonly experienced adverse effects of drug therapy.

Weight gain was found to be the most common adverse effect induced by anti-psychotic therapy. The second generation antipsychotics like olanzapine are known to cause weight

gain. A direct link between cytokines and increase in body mass index (BMI) following olanzapine therapy has also been described.[3] Olanzapine also impaires glucose regulation and causes dyslipidemia which leads to increase in body fat. Increase in serum leptin level was also attributed as a cause of weight gain in patients treated with second generation antipsychotics. Hence it is important that the clinical pharmacist educates the patient about this and counsels about various ways to keep the weight in check during therapy.

Drowsiness is common with antipsychotic medications and is dose related. It can be a cause of poor compliance and, if persistent, can interfere with social and vocational functioning. Many patients become tolerant to the sedative effect over time. Low-potency FGAs and clozapine are the most sedating, with some effect from olanzapine and quetiapine. Somnolence can be alleviated by lowering the dosage, changing to a single bedtime dose, or switching to a medication with less sedative side effect.[4]

Hypotension occurs with all antipsychotic medications, depending on the degree of α1-adrenoreceptor antagonism, particularly with low-potency FGAs and clozapine. It can also occur with risperidone and quetiapine, especially with rapid titration. This effect is more common in older adults (with risk of falls), those on blood pressure medications, and those who have other cardiovascular diseases. With careful dose titration, patients may become tolerant to this effect. Treatment options include decreasing or dividing doses or switching to a medication with a lesser anti adrenergic effect.[5]

Anticholinergic effects such as constipation, drymouth, and were observed. Low-potency FGAs and clozapine are highly likely to cause anticholinergic effects. Olanzapine and quetiapine have been shown to do so at high dosages. When needed, doses can be lowered or divided to help alleviate this problem.[6] Both FGAs and SGAs can impair arousal and orgasm in men and women. FGAs especially have been found to cause erectile and ejaculatory dysfunction in men, including spontaneous, painful, or retrograde ejaculation.[7]

Dystonias are involuntary movements characterized by intermittent or sustained muscle action movements vary from fleeting disturbance to maintained abnormal postures.[8] The muscle stiffness and postural distortion are both painful and uncomfortable and can make patients agitated and frightened. This may be due to interference with presynaptic dopamine receptors, or there may be a mismatch between excess release of dopamine and coincident hypersensitivity of dopamine receptors. Antipsychotics mainly occupy D2 receptors, and the

increased turn over may be expressed through overactivation of the unblocked D1 receptors.[9]

Table -2: ADRs categorized according to age group.

S.NO	Age distribution	%
1.	Young[10-19]	5.6%
2.	Adults [20-45]	45.5%
3.	Middle age[46-60]	43.9%
4.	Geriatric[> 61]	4.9%
	Total	100%

The observations indicated that most ADRs are seen in adult and middle aged patients i.e ranging from 20 to 60 years.

Table 3: WHO probability assessment of ADRs.

S.NO	Assessment	Number of ADR's	%
1.	Certain	4	0.89
2.	Probable	197	44.1
3.	Possible	245	54.9
4.	Unlikely	0	0
5.	Conditional/ Unclassified	0	0
6.	Unassessable/Unclassified	0	0
	Total	446	100

Majority of ADRs were assessed as possible (245) i.e 54.9% followed by probable (197) i.e 44.1% and the least were certain (4) i.e 0.89% according to WHO –UMC causality assessment system.

Table 4: Naranjo's Causality assessment of ADRs.

S.NO	Assessment	Number of ADRs	%
1.	Definite	4	0.89
2.	Probable	180	40.3
3.	Possible	262	58.7
4.	Doubtful	0	0
	Total	446	100

Table 5: Severity Assessment of ADRs by Modified Hartwig and Siegel scale.

S.NO	Assessment	Number of ADRs	%
1.	Mild	286	64.1
2.	Moderate	160	35.8
3.	Severe	0	0
	Total	446	100

Table 6: Preventability criteria of ADRs according to Schumock and Thornton scale.

S.NO	Assessment	Number of ADRs	%
1.	Definitely preventable	286	64.1
2.	Probably preventable	160	35.8
3.	Not Preventable	0	0
	Total	446	100

Analysis of data obtained during the study period for probability and causality assessment of ADRs is shown in tables 2,3,4,5. All the assessment scales of ADRs which are used had put most ADRs in the possible and preventable categories which were mild to moderate in nature. Irrespective of the assessment scales used, majority ADRs could be linked to therapy. Many ADRs could have been prevented if the patients had been educated and counseled about drug therapy. Hence there is a scope for clinical pharmacist to counsel and educate patients regarding the ADRs, help them to try and minimize the adverse effects.

Table 7: ADRs according to organ system.

S.NO	Organ system affected	%
1.	Central and peripheral nervous system	47
2.	Gastrointestinal system	31
3	Anticholinergic	3.0
4	cardiovascular	9.1
5.	Neuromuscular	9.0

Table 6 shows various ADRs categorized as per the organ systems that are affected and as expected majority ADRs were those which affected the nervous system. This is in accordance with what is generally seen in the guidelines.

Table 8: Drugs commonly implicated in ADRs.

Name of the drug	No (% of all ADRs, n=446)
Olanzapine, fluoxetine	135(30.2)
Haloperidol	56(12.5)
Amitryptiline	49(10)
Resperidone	40(8.9)
Fluvoxamine	39(8.8)
Alprazolam, clonazepam	33(7.3)
clozapine	30(6.7)
Bupropion	26(5.8)
Clozapine, Buspirone	26(5.8)
lorazepam,	21(4.7)
Lithium	17(3.8)

Table 8 gives a list of commonly implicated drugs in causing ADRs and fluoxetine and olanzapine were the two drugs which were responsible for 135 ADRs out of a total 446.

CONCLUSION

Clinical Pharmacists have a responsibility in monitoring the ongoing safety of medicines by providing pharmaceutical care and management as a part of their professional practices. Creating awareness about rational drug prescriptions and avoiding poly-pharmacy would help in preventing and appropriate detection of an ADR. This study suggested that a hospital-based monitoring of ADRs by well trained clinical pharmacists is the need of the day for providing an optimum healthcare to the patient. The documented ADR reports and the result of the present study may be helpful for the future researchers to carry out further study in this area as well as cause awareness in the clinicians regarding the ADR profile of the very frequently prescribed class of antipsychotic agents.

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