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Original Research Article

Monitoring of adverse drug reactions in psychiatry outpatient department of a tertiary care hospital in Central India

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ABSTRACT

Background: Adverse drug reactions (ADRs) are prevalent in patients taking psychotropic medications and can occur even at the normal doses used in the management of acute and maintenance phases of psychiatric disorders. Pharmacovigilance have cardinal role in alerting the healthcare providers from the possible ADRs and thus protecting the patients who are using psychotropic medications. To Monitor and estimate the incidence and nature of ADRs in psychiatry OPD of tertiary care hospital in central India and assess the causality, preventability and severity of documented ADRs.

Methods: A prospective observational study was conducted in psychiatry out-patient department (OPD). Patients diagnosed with any psychiatric disorder and receiving psychotropic medications was included in the study. The recorded data were filled in the ADR form obtained from pharmacovigilance program of India (PvPI). Causality assessment was done using Naranjo scale and severity was assessed using Hartwig scale and preventability assessment using modified Schumock and Thornton's scale.

Results: The incidence rate of ADR was found to be 15.8%. A total of 61 ADRs were documented. Weight gain 14 (18.1%) followed by nausea 11 (14.2%) was the most commonly reported ADR. Atypical antipsychotics were the most common class of psychotropic drugs implicated in ADRs. Clonazepam 21 (27.2%) followed by amitriptyline 20 (25.9%) were associated with a maximum number of ADRs. Majority of the suspected ADRs were probable in nature (40.9%) followed by possible type (31%).

Conclusions: Study revealed a moderate incidence of ADRs in patients attending the psychiatry OPD. Majority of the ADRs reported during the study were mild in nature and definitely preventable type.

Keywords: Adverse drug reaction, Pharmacovigilance, Psychiatry outpatient department, Psychotropic medications

INTRODUCTION

According to the WHO, adverse drug reaction (ADR) is defined as any response which is noxious and unintended and occurs at dosages normally used in humans for prophylaxis, diagnosis, or therapy for disease or for the modification of physiological function.¹ ADRs are notable cause of morbidity and mortality in patients of inpatients and outpatients departments.² In Indian population the incidence of ADRs is ranges from 1.8% to 25.1% with 8% hospitalization.³

ADRs are prevalent in patients taking psychotropic medications and can occur even at the normal doses used in the management of acute and maintenance phases of psychiatric disorders.⁴ Consequences of these ADRs are impairment of quality of life, poor adherence to medications, physical morbidity and in extreme cases it can be fatal.⁵

The incidence, nature and occurrence of ADRs to various psychotropic medications have reported by many studies.⁶⁻⁸ Good number of these studies has also reported

the incidence of ADRs in patients visiting psychiatry outpatient departments (OPDs).⁸⁻¹⁰ The study reported by Solanke et al, the overall incidence rate of ADRs was found to be 5.01% in psychiatry OPD of tertiary referral center in central India.⁸

The awareness of the health care providers regarding ADRs of the psychotropic agents and its management can promote the safe and rational use of these agents. Pharmacovigilance has a cardinal role in alerting the healthcare providers from the possible ADRs and thus protecting the patients who are using psychotropic medications.¹¹ Pharmacovigilance means a science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other medicine-related problem.¹²

Therefore, the ultimate goal of our study is to enhance and strengthen the pharmacovigilance activity in tertiary care hospital of central India and encourage the role of doctors in ADR monitoring and reporting.

METHODS

A prospective observational study was conducted in psychiatry out-patient department (OPD) of Government Medical College Nagpur, between October 2016 and December 2016. Patients of all age groups and both the gender, diagnosed with any psychiatric disorder and receiving psychotropic medications and registered in the psychiatry OPD were monitored and included in the study. ADRs noticed by the treating psychiatrist, reported by the patient or their caretakers during regular patient consultation were documented. The required data was collected from the patient case files as well as from the patients themselves and their caretakers if required.

The recorded data were filled in the ADR form obtained from pharmacovigilance program of India (PvPI) and central drug standard control organization (CDSCO) website. Patient's various details such as demographic information; disease characteristics, history of ADR, medication history, and other relevant information were noted. Patients suffering from malignancies, drug abusers, terminally ill and mentally retarded patients were excluded from study. The data were analyzed; causality assessment was done using Naranjo scale and severity was assessed using Hartwig et al, scale and preventability assessment using modified Schumock and Thornton's Scale.^{13,14} Confidentiality of the information will be assured throughout the study.

RESULTS

A total of 385 patients were monitored. Among the 61 patients who experienced ADR to psychotropic medications, 24 (39.34 %) were males and 37 (60.50%) were females. The maximum numbers of ADRs were documented in the age group of 18-39 years (41%) followed by 50-59 years (19.6%). The incidence of ADRs

at outpatient psychiatry department was found to be 15.8%. A total of 77 ADRs were observed during the study period. Majority of the patients 48 (78.6%) experienced at least one ADR. Weight gain 14 (18.1%) was the most commonly suspected ADR followed by nausea 11 (14.2%), constipation (9.09%), somnolence (6.4%), (Tables 1).

Table 1: Spectrum of suspected adverse drug reactions (ADRs) noted among 61 patients (n=77).

Type of ADR	N (%)
Weight gain	14 (17.5)
Nausea	11 (13.7)
Constipation	7 (8.7)
Somnolence	5 (6.25)
Restlessness, abdominal discomfort, increase appetite	4 (5)
Headache, dizziness, irritability, acidity, sedation	3 (3.75)
Vomiting	2 (2.5)
Insomnia, tinnitus, decrease appetite, fatigue, tremors, rigidity, heaviness	1 (1.25)

ADR: adverse drug reaction, N: total number of ADRs.

Table 2: Drugs responsible for 77 adverse drug reactions noted among 61 patients.

Name of drug	% of ADR
Clonazepam	17.94
Amitriptyline	17.09
Escitalopram	12.82
Olanzapine	9.4
Risperidone	7.12
Sodium valproate, fluoxetine, vilazodone	10.2
Imipramine, sertraline, lorazepam, trihexiphenidyl	10.2
Lurasidone, pregabalin, chlorpromazine, levosulpride, naproxen, folic acid, mosapride	11.99
Aripiprazole, phenytoin, quetiapine, flunarizine, clozapine, lithium	5.12

ADR: adverse drug reaction.

Weight gain has been reported in 14 cases. However, the weight (pre- and post-treatment) details of only 10 patients were available during documentation. The average weight of the patients before initiating psychotropic drugs was found to be (63.7±12.1) kg, whereas after receiving suspected psychotropic therapy, it was found to be (76.9±14.9) kg. This difference in the weight of the patients after receiving the suspected psychotropic treatment was found to be highly significant (p<0.001).

Clonazepam 21 (27.2%) was the most commonly implicated drug in ADR followed by amitriptyline 20 (25.9%) and escitalopram 15 (19.4) and olanzapine 11 (14.2%) (Table 2). Atypical antipsychotics followed by selective serotonin reuptake inhibitors were the most commonly prescribed psychotropic medications in the study.

Depression (31.1%) was the most commonly diagnosed psychiatric condition in patients who developed ADRs followed by schizophrenia (16.3%) and migraine. It was found that central nervous system (CNS) was the most commonly affected organ due to ADRs followed by gastrointestinal system.

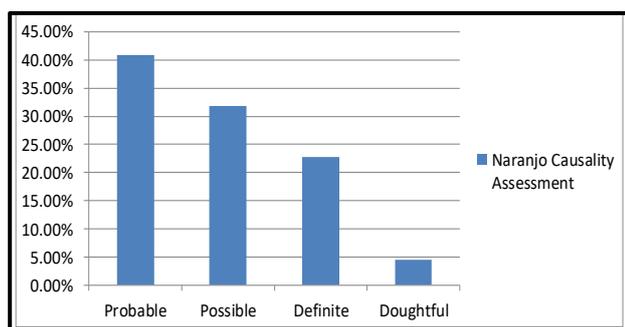


Figure 1: Naranjo causality assessment scale.

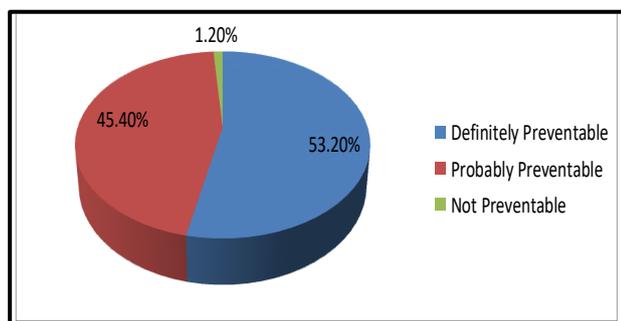


Figure 2: Modified Schumock and Thornton scale.

Causality assessment of suspected ADRs was done using Naranjo causality assessment scale. Majority of the suspected ADRs were probable in nature (40.9%) followed by possible type (31%) (Figure 1). Severity assessment of suspected ADRs was done using Hartwig’s severity assessment scale. Majority of the suspected ADRs were mild in nature 51 (66.2%) followed by moderate type 24 (31.1%). Preventability assessment of suspected ADRs was done using Modified Schumock and Thornton scale. Majority of the suspected ADRs 41 (53.2%) were definitely preventable type followed by probably preventable 35 (45.4%) (Figure 2).

DISCUSSION

In present study, the incidence of ADR was calculated to be 15.8%. However, many studies have reported an overall incidence rate of 5.01-35% in psychiatry OPDs.¹⁵

In contrast to our findings, a study conducted by Patel et al, reported an incidence rate of 0.69% in psychiatry outpatients.¹⁶ The females showed high incidence of ADRs than males which is in accordance with the previous studies.^{8,17} This increased risk may be due to gender-related differences in pharmacokinetic, immunological, hormonal factors and differences in the use of medications.

Atypical antipsychotics followed by selective serotonin reuptake inhibitors were the most commonly prescribed psychotropic medications in the study. Which is in line with previous studies reported by Rothschild et al, and Sengupta et al.^{4,18} This can be explained by its high utilization for schizophrenia and bipolar disorders in our setup.

Weight gain was the most commonly suspected ADR followed by nausea and constipation. Which is supported by studies who also reported weight gain as most commonly reported ADR.^{8,17} As reported in the literature the possible mechanisms for weight gain include 5HT 2c and H1 antagonism.¹⁹ Besides that improvement of the underlying mental disorder like depression promotes increase in appetite and weight gain. It proposed that switching the medication or psychotherapy, education, and healthy lifestyle will be advantageous in treating the drug-induced weight gain.²⁰

In present study, causality assessment of many ADRs was probable in nature. Majority of suspected ADRs were mild and were definitely preventable type. In accordance with our study, study conducted by Mishra et al, has reported higher number of ADRs, which are mild in nature.⁷ But study conducted by Prajapati et al, accounted higher number of ADRs, which were moderate in nature.²¹ In our study, majority of the suspected ADRs were definitely preventable. In contrast to our findings, a study conducted by Nithya et al, reported that all the ADRs to psychotropic drugs were not preventable type.²² In another study conducted by Lahon et al, majority of the ADRs were probably preventable.²³

The main limitation of the present study was short duration of the study period. Study duration of more than 1 year could draw more inferential result as there would be wide spectrum of ADRs to wide variety of medications. In addition, majority of the ADRs identified during study duration were mild in nature. No fatal ADRs were documented in the outpatient clinic, as the patients who develop serious ADRs will be admitted to emergency room directly followed by inpatient department.

CONCLUSION

The present study gives a brief overview about occurrence of adverse drug reactions due to psychotropic medications. Weight gain was the most commonly suspected ADR. Atypical antipsychotics were the most

commonly implicated drugs causing ADRs. The study revealed that majority of the ADRs reported during the study were mild in nature and definitely preventable type. Regular strenuous monitoring of ADRs in psychiatry OPD settings by might help in early sensing of ADRs. It minimises the risk caused by ADR and thereby it may improve patient's quality of life, lessens treatment cost and escalates compliance to the treatment.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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