Original Article

Adverse Drug Reactions in Psychiatry Outpatient Department of a Tertiary Care Hospital in Western Uttar Pradesh: An Observational Study

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ABSTRACT

Objective: Psychiatric disorders are chronic in nature which require medications for a long duration. These medications have been associated with many adverse events. Failure to recognize an adverse drug reaction (ADR) exposes the patient to continuing risk of ADR, leading to a significant impact on patient's quality of life. Thus, the present study carried out to identify the pattern of ADRs reported due to psychotropic medication. **Methods:** This was a cross-sectional study conducted to analyze ADRs reported from the psychiatry department of a tertiary care teaching hospital from October 2021 to March 2022. **Findings:** A total of 137 ADRs were identified from 102 patients. Majority of the ADRs were reported from antidepressants, with paroxetine being the leading offending drug. The central nervous system was most commonly affected, and dizziness (13.13%) was the most common ADR noted. On causality assessment, 97 ADRs (70.8%) were of "possible" type. Almost half of the patients with ADRs (47.5%) recovered spontaneously. No ADR encountered turned out to be fatal. **Conclusion:** The present study revealed that the majority of ADRs reported from psychiatry OPD were mild in nature. We reinforce the identification of ADR is crucial in the hospital setting process as it gives an insight into the risk-benefit ratio for rational use of the drug.

KEYWORDS: *Adverse drug reactions, adverse event, antidepressants, Paroxetine*

INTRODUCTION

Mental illnesses are one of the primary causes of nonfatal disease burden in India. In 2017, one in every seven Indians suffered from mental illnesses of varying severity.[1] Mental diseases necessitate the use of drugs for extended periods, ranging from months to years.[2] Because of the prolonged duration of treatment, it is linked with a wide spectrum of adverse drug reactions (ADRs). ADRs associated with psychotropic medicines can occur even at standard dosages used in the treatment of acute and chronic mental problems and can lead to noncompliance and, in certain cases, cessation of therapy.[3] In psychiatry units, pharmacovigilance can play a critical role in identifying ADRs and alerting clinicians to the potential and circumstances of such occurrences thus saving the patients from preventable harm.[4] Spontaneous reporting systems for ADR monitoring can identify serious as well as rare ADRs. It has prompted multiple early safety signals for antidepressants and antipsychotics, leading to modifications in their labeling for warnings, precautions, and contraindications.[5] As a result, ADR monitoring aids in the development of appropriate interventional programs to manage, prevent, and minimize the risk of developing ADRs, hence lowering therapeutic costs.[4]

The studies conducted in this field from India are scarce. Hence, this study was planned to analyze data to gain

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a better understanding of the nature of ADRs in the psychiatry department.

Methods

This was a cross-sectional study carried out in the psychiatry outpatient department of a tertiary care teaching hospital for 6 months (October 2021 to March 2022). The study protocol was reviewed and approved by the Institutional Ethics Committee (GIMS/IEC/HR/2021/34 dated 24.9.21). Patients of all age groups and of both sexes, diagnosed with any psychiatric disorder and receiving any psychotropic medications, willing to participate in the study were included in the study. Patients not taking any psychotropic medications, suffering from malignancies/ terminally ill patients, mentally retarded patients and patients not willing to participate were excluded from the study. Patients not accompanied by a family caregiver were also excluded from the study. All the patients attending psychiatry OPD and satisfying the inclusion criteria were monitored for ADRs on 5 fixed days in a week by the study investigators from 9:00 am to 1:00 pm.

ADRs reported by the patients were recorded. Apart from this, ADRs documented by the clinical psychiatrist were also noted. Patient-related information such as demographic details, relevant medical/past history, diagnosis, treatment (dose, frequency, date of start), laboratory investigation reports, ADR details including the nature of the reaction, date of onset, severity, the treatment offered, outcome, suspected drug including its dose, pharmaceutical dosage form, route of administration, list of concomitant drugs, information on the challenge and dechallenge, length of hospital stay were recorded in the suspected ADR form.

Naranjo probability scale was used to determine the relationship between the alleged ADR and medication. The scale consists of a questionnaire containing 10 questions with the options yes, no and do not know. The total score from this questionnaire describes the range as >9: Definite, 5–8: Probable, and 1–4: Possible.[6]

Hartwig Severity Scale was used to determine the severity of the ADRs.[7] ADRs were graded as mild (level one, two), moderate (level three, four, five), and severe (level six, seven) according to this scale. Suspected ADRs were also listed as serious and nonserious.[8]

The updated Schumock and Thornton scale was used to assess the preventability of ADRs.[9]

Results

During the study period of 6 months, 478 patients attended the Psychiatry outpatient department. A total of 102 patients (21.3%) were suspected of having at least one ADR. 137 ADRs reported from 102 patients were included for analysis. Out of the total patients, 51.96% were males and 48.03% were females. The median age of the patients was 39 years.

Depression (37.25%) was the most common clinical diagnosis among these cases, followed by anxiety (30.39%) as shown in Table 1. Thirty-one different kinds of treatment-emergent ADRs were encountered in the patients, as listed in Table 2. Central nervous system was most commonly affected, and dizziness (13.13%) was the commonest ADR noted, closely, followed by uneasiness (11.6%). Among the drugs incriminated, anti-depressants were the most common drug class implicated. Paroxetine (24.2%) was the most common drug causing ADRs, followed by escitalopram (20.2%), as summarized in Table 3. Causality assessment using the Naranjo probability scale revealed that 40 ADRs (29.2%) belonged to "probable" category, whereas 97 ADRs (70.8%) were of "possible" type. As per the Hartwig scale, 76.7% ADRs were mild and 18.9% were moderate. No ADR encountered turned out to be fatal. 50.36% of ADRs were probably preventable.

Sixty-five ADRs (47.5%) recovered spontaneously. Six ADRs (4.38%) were serious. Some of the events, such as hair loss and gritty sensation in the eyes, were temporarily disabling but were managed with corrective medication. Table 4 depicts the list of drugs used to manage ADRs. All the patients with ADRs showed recovery.

Some of the rare ADRs were also noted during the course of the study. A 33-year-old male patient on tablet clozapine had hemoptysis after 15 days of initiation of therapy. The patient recovered after supportive therapy. In another case, a 28-year-old female patient was on tablet olanzapine for the past 1 week reported urinary frequency and showed recovery after the medication was stopped. An elderly patient taking Lithium for 4 years had severe dehydration and showed signs of spasticity which resulted in permanent disability even after stopping the medication.

Table 1: Diagnosis of patients who reported adverse drug reactions

Psychiatric disorder	Number of patients (%)
Obsessive-compulsive disorder	6 (5.88)
Depression	38 (37.25)
Tension headache	6 (5.88)
Anxiety	31 (30.39)
Dhat syndrome	2 (1.96)
Dependence	2 (1.96)
Psychosis	13 (12.75)
Bipolar disorder	4 (3.92)

Table 2: Spectrum of suspected adverse drug reactions noted among 102 patients

Type of ADR	Number of ADRs (%)
Spasticity	2 (1.5)
Delirium	2 (1.5)
Hemoptysis	1 (0.7)
Seizure	1 (0.7)
Urinary frequency	1 (0.7)
Gritty sensation	1 (0.7)
Oculogyric	1 (0.7)
Hair loss	4 (2.9)
Curling	1 (0.7)
Awakening	2 (1.5)
Constipation	10 (7.3)
Urinary incontinency	2 (1.5)
Weight loss	1 (0.7)
Weight gain	5 (3.6)
Amenorrhoea	3 (2.2)
Galactorrhoea	1 (0.7)
Facial edema	1 (0.7)
Tremors	3 (2.2)
Akathisia	2 (1.5)
Agitation	2 (1.5)
Dystonia	2 (1.5)
Hypertension	1 (0.7)
Erectile dysfunction	10 (7.3)
Diminished sexual desire	10 (7.3)
Dizziness	18 (13.1)
Uneasiness	16 (11.7)
Sedation	12 (8.8)
Headache	12 (8.8)
Vertigo	7 (5.1)
Dryness of mouth	2 (1.5)
Drooling of saliva	1 (0.7)

ADRs=Adverse drug reactions

Discussion

The present study was an active surveillance for the collection of ADRs due to various antipsychotic drugs in addition to the ADRs spontaneously reported by clinicians. The overall incidence rate of ADRs in the present study was found to be 21.3%. The evidence from the literature suggests that the incidence of ADRs in psychiatric OPDs in India varies from 6.41% to 41.9%.[10-12] The disparity in the incidence rate reported from different studies might be due to variable study duration and reporting culture. Studies using the spontaneous reporting method generally detect lower incidences of ADRs. In the present study, 51.96% of male patients and 48.03% of female patients reported ADRs, which is similar to that reported in the study by Sridhar *et al*.[3]

In the current study, the median age of patients with ADRs was found to be more than or equal to 30 years which is similar to other studies.[10,13] This finding may be because patients of this age group pay more attention to their health and use far more healthcare services.

CNS adverse effects (59.85%), such as dizziness (13.1%), followed by uneasiness (11.7%), sedation, and headache were the most common symptoms in the present study, as these drugs act on CNS. Similar to this study, Gawali *et al*. found the most common organ system affected by ADRs to be CNS.[10] Ambwani *et al*. as well reported sedation as the most common ADR.[14] Several studies have reported weight gain as the most common symptom. This difference in the findings could be due to the difference in the prescribing pattern of psychotropic medications and may be influenced by the number and type of psychiatric patients visiting the OPD.[3,11]

The major causative pharmacology drug group was antidepressants. This is in concordance with the study done by Sharma *et al*.[13] In the present study, paroxetine (24.2%) was the most common drug causing ADRs, followed by escitalopram (20.2%). In contrast to the present study, several studies have reported antipsychotic drugs as the most common drug group causing most of the ADRs.[4,10-12] The commonly diagnosed conditions and the differences in the prescribing practices determine the class of drugs that are used, which in turn determine the type of ADR which is seen.

Causality assessment using the Naranjo probability scale revealed that 40 ADRs (29.2%) belonged to "probable" category, whereas 97 ADRs (70.8%) were of "possible" type. This observation is supported by previous studies.[3,14] Similar to other studies majority of ADRs were of mild nature.[3,10,11] In contrast to the present study, Prajapati *et al*. reported 65.85% of ADRs to be of the moderate category.[12] In the study, only six ADRs were categorized as Serious. Sharma *et al*. reported two serious cases, while Patel *et al*. reported one out of five ADRs to be serious.[5,13] Majority of the suspected ADRs 69 (50.36%) were of probably preventable type. Mahakalkar *et al*. reported ADRs to be definitely preventable.[11] However, Sridhar *et al*. and Prajapati *et al*. reported the majority to be nonpreventable.[3,12] The preventability factors involved in the study by Prajapati *et al*. were inappropriate doses and poor patient compliance.[12]

Many factors play a crucial role in the occurrence of ADRs, understanding them enables health-care professionals to choose the most appropriate medication for their patients. Despite limitations, spontaneous reporting of ADRs is a useful tool for monitoring ADRs and generating signals on drug safety. These can

Table 3: Drugs responsible for 137 adverse drug reactions noted among 102 patients

Drugs causing ADRs	Total patients who reported ADRs, *n* (%)
Aripiprazole	5 (5.05)
Duloxetine	10 (10.10)
Fluoxetine	7 (7.07)
Escitalopram	22 (22.22)
Venlafaxine	3 (3.03)
Lithium	2 (2.02)
Valproate	4 (4.04)
Risperidone	11 (11.11)
Olanzapine	5 (5.05)
Haloperidol	3 (3.03)
Paroxetine	25 (25.25)
Lorazepam	1 (1.01)
Clozapine	1 (1.01)
Amitriptyline	2 (2.02)
Topiramate	1 (1.01)

Table 4: Corrective medications

Drug	Percentage use
Benzodiazepines	66.6
Trihexyphenidyl	24.3
Propranolol	5.7
Antiepileptics	1.4
Others	2

help to identify opportunities for improving the safety of drugs.

The limitation of the present study was its short duration. As the study was OPD based, transient ADRs were likely to be missed.

The present study presents a brief outline of ADRs in the psychiatry outpatient department. Antidepressants were the most commonly implicated drug group causing ADRs. Majority of the ADRs reported during the study were mild in nature and definitely preventable type. Little evidence has been reported about the burden of ADRs with the use of psychiatric drugs in practice. ADRs are a preventable cause of harm to patients and an unnecessary waste of health-care resources. Potential ADRs should be part of every differential diagnosis so as to minimize the risk caused by ADR and thereby improve patient's quality of life.

Authors' Contribution

Dr Deepti Chopra, Dr Jaspreet Kaur Sidhu, Dr Kiran Jakhar and Dr C D Tripathi contributed in the concept and design of the study. Dr Jaspreet Kaur Sidhu, Dr Deepti Chopra, Dr Kiran Jakhar, Dr Aditi Dhote, Mohammad Shadman, Vishakha Babber did data collection and literature review. Dr Jaspreet Kaur Sidhu, Dr Deepti Chopra, Dr Kiran Jakhar, Dr Aditi Dhote, Dr C D Tripathi, Vishakha Babber and Mohammad Shadman analyzed the data and prepared the manuscript. All authors approved the final manuscript.

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Conflicts of interest

There are no conflicts of interest.

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