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# CLINICAL SPECTRUM AND SEVERITY OF ANTIPSYCHOTIC-INDUCED ADVERSE DRUG REACTIONS: A PROSPECTIVE STUDY

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## ABSTRACT

**Background:** Psychotropic drugs are essential in the management of psychiatric disorders, yet they are frequently associated with adverse drug reactions (ADRs), potentially affecting compliance and treatment outcomes. **Objective:** To evaluate the outcomes, severity, and causality of ADRs associated with psychotropic medications in a psychiatry department of a tertiary care teaching hospital in North-West India. **Methods:** A prospective observational study was conducted over 6 months in the psychiatry outpatient and inpatient departments at JLN Medical College, Ajmer. ADRs were identified, documented, and analysed using the WHO-UMC causality scale and Hartwig's severity scale. **Results:** Among 105 patients, 264 ADRs were reported. The most common ADRs included slurring of speech (35.2%), rigidity (18.1%), tremors (17.1%), and weight gain (13.3%). Antipsychotics, particularly Olanzapine (22.8%), Haloperidol (19%), and Risperidone (14.3%), were the leading offending agents. Most ADRs were mild to moderate in severity. **Conclusion:** Psychotropic drugs, especially antipsychotics, are associated with a wide range of ADRs. Continuous monitoring, early identification, and patient education can reduce ADR burden and improve adherence.

**KEYWORDS:** Psychotropic drugs, Adverse drug reactions, Pharmacovigilance, Hartwig scale, WHO-UMC scale.

## INTRODUCTION

Psychiatric disorders such as schizophrenia, bipolar disorder, depression, and anxiety represent a significant proportion of the global disease burden. According to the World Health Organization, approximately one in eight individuals worldwide is affected by a mental health condition. In India, psychiatric illnesses impact nearly 14% of the population and often require long-term pharmacotherapy with psychotropic medications.

Psychotropic agents—comprising antipsychotics, antidepressants, mood stabilizers, and anxiolytics—are essential for the management of psychiatric disorders. Nonetheless, their use is commonly associated with adverse drug reactions (ADRs), which may range from mild (e.g., sedation, gastrointestinal disturbances) to severe (e.g., extrapyramidal symptoms, metabolic abnormalities, and cardiac disturbances). These ADRs frequently contribute to poor treatment adherence, increased morbidity, and a higher overall burden on healthcare systems.

Despite the establishment of the Pharmacovigilance Programme of India (PvPI), ADRs associated with psychotropic drugs often remain underreported. Contributing factors include patient-related stigma and limited awareness or training regarding pharmacovigilance within healthcare settings.

Given the frequent use of polypharmacy, the complexity of treatment regimens, and the vulnerability of psychiatric patients, it is essential to systematically monitor and report ADRs in this subgroup. Therefore, the present study was undertaken to assess the prevalence, severity, and causality of ADRs associated with psychotropic medications in the Psychiatry Department of a tertiary care teaching hospital in Northwest India. The findings aim to strengthen local pharmacovigilance efforts and contribute to safer and more rational prescribing practices in psychiatric care.

## MATERIALS AND METHODS

### Study Design and Duration

A prospective, observational study was conducted over a 6-month period (Nov 2022–Apr 2023).

### Study Site

Department of Psychiatry, JLN Medical College and Hospital, Ajmer, Rajasthan.

### Inclusion Criteria

- Patients of all ages and genders diagnosed with psychiatric disorders as per ICD-10 criteria.
- Patients receiving psychotropic medications.
- Patients (or their guardians) who provided informed consent.

### Exclusion Criteria

- Patients with incomplete medical records.
- Patients who discontinued treatment prematurely.
- Patients unwilling to participate.

### Data Collection

Data was recorded using the standard ADR reporting form (PvPI V1.4). Causality and severity were assessed using the WHO-UMC scale and Hartwig’s scale, respectively.

**Sample Size**

Based on a 43.5% estimated prevalence and a 10% margin of error at a 95% confidence interval, the minimum required sample size was 94. A total of 105 patients were enrolled.

**RESULTS**

A total of 105 patients receiving psychotropic medications were included in the study. Outpatients comprised 69.5% of the sample, and 30.5% were inpatients. **[Table 1] [Figure1]**

**Table 1: Distribution of cases according to OPD/IPD.**

| Parameter | No. of Patients | Percentage |
|---|---|---|
| **OPD** | 73 | 69.52 |
| **IPD** | 32 | 30.48 |
| **Total** | 105 | 100.00 |

*n = 105; OPD: Outpatient Department; IPD: Inpatient Department.*

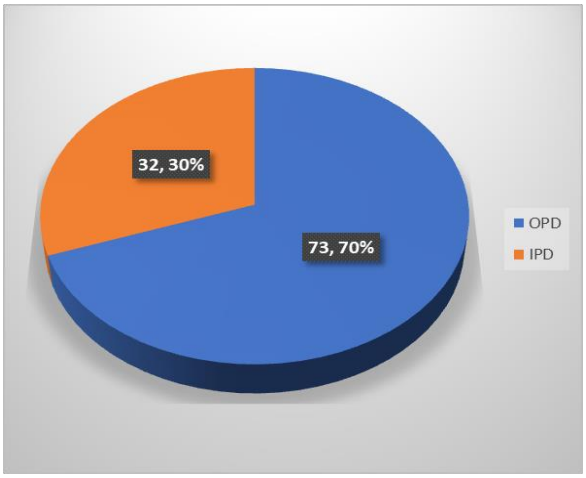


**Figure 1: Distribution of cases according to OPD/IPD attendance.**

A total of 264 adverse drug reactions (ADRs) were reported. The most commonly observed ADRs were slurring of speech (35.2%), rigidity (18.1%), and gross tremors in hands (17.1%). Other frequently noted reactions included weight gain (13.3%), akathisia (12.4%), and gastrointestinal complaints such as nausea or constipation (11.4%). **[Table 2] [Figure 2]**

**Table 2: Distribution of cases according to ADR.**

| ADR | No. of Patients | Percentage |
|---|---|---|
| Slurring of speech | 37 | 35.24 |
| Rigidity | 19 | 18.10 |
| Gross tremors in hand | 18 | 17.14 |
| Akathisia | 13 | 12.38 |
| Weight gain | 14 | 13.33 |
| Nausea | 12 | 11.43 |
| Constipation | 12 | 11.43 |
| Excessive salivation | 9 | 8.57 |
| Diarrhoea | 8 | 7.62 |
| Indigestion | 8 | 7.62 |
| Increase salivation | 8 | 7.62 |
| Vomiting | 7 | 6.67 |
| Acidity | 8 | 7.62 |

| | | |
|---|---|---|
| Fever | 5 | 4.76 |
| Decrease appetite | 4 | 3.81 |
| Fine tremors | 3 | 2.86 |
| Increased CK-NAAC | 4 | 3.81 |
| Abdominal cramps | 3 | 2.86 |
| Fine tremors in both hands | 5 | 4.76 |
| Frequency of bowel decrease | 1 | 0.95 |
| Restlessness | 3 | 2.86 |
| Dry mouth | 2 | 1.90 |
| Gastritis | 2 | 1.90 |
| Generalized swelling | 2 | 1.90 |
| Hyperacidity | 2 | 1.90 |
| Increase sweating | 2 | 1.90 |
| Tardive dyskinesia | 2 | 1.90 |
| Antipsychotic induced Parkinson's-tremors | 1 | 0.95 |
| Gum hypertrophy | 1 | 0.95 |
| Opisthotonus | 1 | 0.95 |

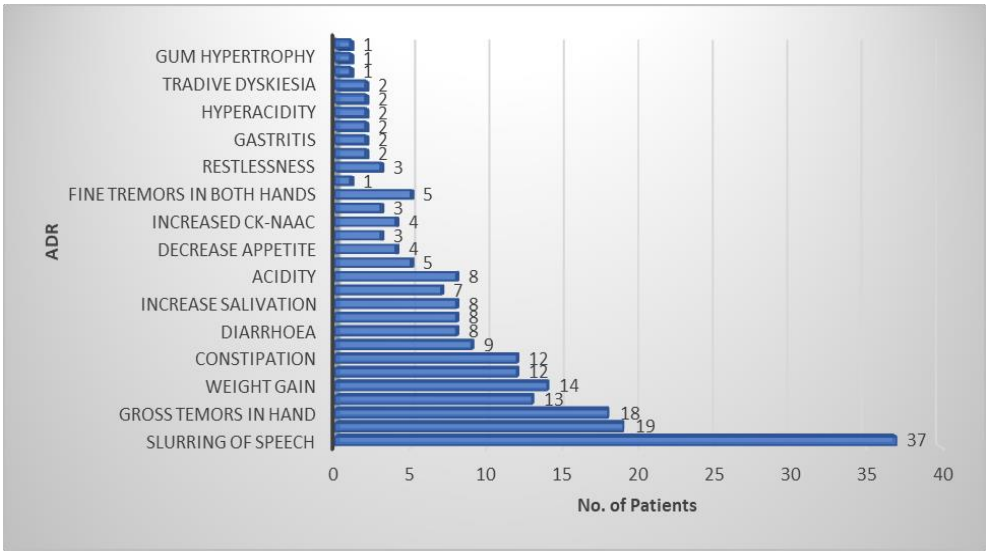


**Figure 2: Distribution of cases according to ADR.**

Olanzapine was implicated in 22.8% of ADRs, followed by Haloperidol (19%), Risperidone (14.3%), Sodium Valproate (8.6%), Fluoxetine (6.7%), Escitalopram (6.7%), and Aripiprazole (3.8%). **[Table 3] [Figure3]**

**Table 3: Distribution of cases according to drugs.**

| Drug Causing ADR | No. of Patients | Percentage |
|---|---|---|
| Haloperidol | 20 | 19.05 |
| Risperidone | 15 | 14.29 |
| Olanzapine | 24 | 22.86 |
| Fluoxetine | 7 | 6.67 |
| Sodium Valproate | 9 | 8.57 |
| Escitalopram | 7 | 6.67 |
| Aripiprazole | 4 | 3.81 |
| Others | 19 | 18.10 |
| Total | 105 | 100.00 |

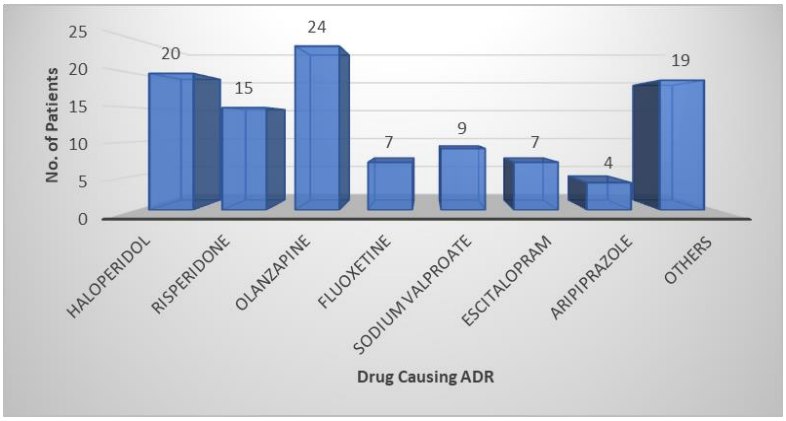


**Figure 3: Distribution of cases according to drugs.**

Based on Hartwig's Severity Scale, 41% of ADRs were mild, 50% moderate, and 9% severe. Causality assessment using the WHO-UMC scale showed 54% of ADRs were probable, 42% possible, and 4% unlikely **[Table 4] [Figure 4]**

**Table 4: Distribution of cases according to Hartwig and Sigel's Severity Assessment Scale.**

| Hartwig Severity Assessment Scale | No. of Patients | Percentage |
|---|---|---|
| **Mild** | 37 | 35.24 |
| **Moderate** | 68 | 64.76 |
| **Total** | 105 | 100.00 |

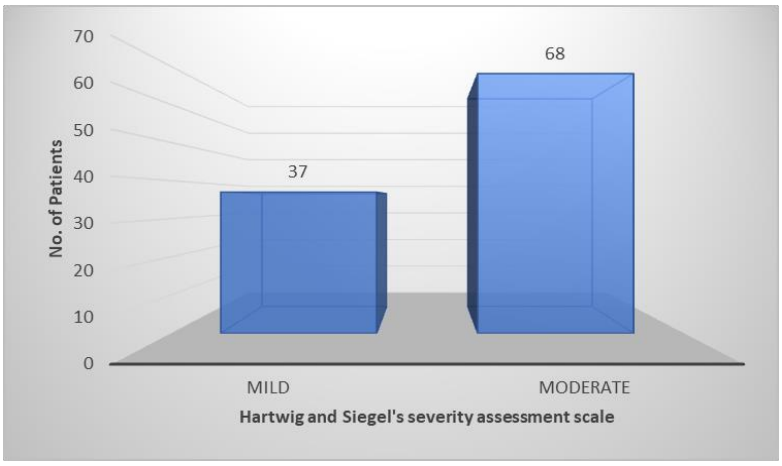


**Figure 4: Distribution of cases according to Hartwig and Sigel's Severity Assessment Scale.**

## DISCUSSION

This study demonstrates a considerable incidence of adverse drug reactions (ADRs) associated with antipsychotic medications, particularly atypical agents. The most frequently reported ADRs—slurred speech (35.24%), rigidity (18.10%), and tremors (17.14%)—are characteristic of extrapyramidal symptoms and were predominantly linked to haloperidol and risperidone.[8] Olanzapine and selective serotonin reuptake inhibitors (SSRIs) such as escitalopram and fluoxetine were commonly associated with weight gain and gastrointestinal disturbances.[9,10]

Most ADRs observed were mild to moderate in severity and manageable through dose adjustment or supportive treatment. Nevertheless, the findings underscore the need for continuous monitoring, especially in patients receiving multiple psychotropic agents. Notably, a larger proportion of ADRs occurred in outpatients (69.52%) compared to inpatients (30.48%), emphasizing the importance of vigilance in both clinical settings.

Among psychiatric diagnoses, bipolar affective disorder (32.38%) was most prevalent, followed by schizophrenia (23.81%) and depression (21.90%), which is in concordance with the observations by Ashik A et al.[11] This pattern reflects the high use of antipsychotics and mood stabilizers in these conditions.

Drug-wise, olanzapine (22.86%) was the most frequent contributor to ADRs, followed by haloperidol (19.05%) and risperidone (14.29%). These findings align with earlier study by Patel M et al.[12] and Lucca et al.,[13] reaffirming the prominent role of these agents in ADR profiles.

Severity assessment using the Hartwig scale revealed that the majority of ADRs were moderate (64.76%), with 35.24% being mild—comparable to findings by Ramakrishnaiah et al.[14]

## CONCLUSION

Psychotropic drugs, particularly antipsychotics, are frequently associated with ADRs in psychiatric patients. Early identification, patient education, and routine pharmacovigilance can improve drug safety, enhance treatment adherence, and reduce healthcare burden.

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### Conflicts of Interest

None declared.

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