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IMPACT OF PSYCHOTROPIC DRUG-INDUCED ADVERSE DRUG REACTIONS ON QUALITY OF LIFE IN PSYCHIATRIC PATIENTS

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ABSTRACT: Background: Psychotropic medications are integral to managing psychiatric disorders; however, their associated adverse drug reactions (ADRs) can significantly impair patients' quality of life (QOL). **Objective:** To evaluate the spectrum of ADRs linked to psychotropic drug use and assess their impact on QOL among psychiatric patients at a tertiary care centre. **Methods:** In this cross-sectional observational study, 105 patients from the psychiatry outpatient and inpatient departments of JLN Medical College, Ajmer, were assessed. ADRs were documented using standard Pharmacovigilance Programme of India (PvPI) reporting formats. The WHOQOL-BREF questionnaire evaluated QOL. Causality and severity of ADRs were determined using the WHO-UMC scale and Hartwig's criteria, respectively. **Results:** A total of 264 ADRs were recorded, with slurred speech (35.2%), rigidity (18.1%), and tremors (17.1%) being the most frequent. Antipsychotics, particularly olanzapine (22.8%) and haloperidol (19%), were commonly implicated. Most ADRs were non-serious (91.4%) and classified as probable (54%) or possible (42%). Patients experiencing moderate-to-severe ADRs showed significant declines in physical ($p=0.004$) and psychological ($p=0.008$) QOL domains. **Conclusion:** ADRs from psychotropic medications adversely affect patients' QOL, especially in physical and psychological aspects. Regular monitoring and individualized therapeutic strategies are crucial to mitigate these effects and enhance treatment outcomes.

INTRODUCTION: Psychiatric disorders, including depression, bipolar disorder, schizophrenia, and anxiety related conditions, are chronic and often debilitating illnesses that require long-term pharmacological management.

The increasing use of psychotropic drugs such as antipsychotics, antidepressants, mood stabilizers, and anxiolytics has led to a parallel rise in adverse drug reactions (ADRs), which can significantly impact treatment outcomes and patient well-being ^{1, 2}.

Although these medications are effective in controlling symptoms and preventing relapse, the occurrence of ADRs often limits their therapeutic utility and contributes to poor adherence ³. ADRs associated with psychotropic medications range in severity and type from mild symptoms like dry

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mouth or sedation to serious issues such as extrapyramidal symptoms, weight gain, metabolic syndrome, and sexual dysfunction ⁴. These side effects not only reduce functional capacity and productivity but also diminish psychological resilience, particularly in psychiatric patients who may already suffer from cognitive impairment, emotional instability, and inadequate social support ⁵. Quality of Life (QOL), a multidimensional construct involving physical, psychological, social, and environmental domains, has emerged as a key outcome in mental health research ⁶. Instruments such as the WHOQOL-BREF provide valuable insights into patients' subjective experiences, allowing clinicians to evaluate the broader impact of treatment beyond symptom relief ⁷. Emerging evidence indicates that ADRs have a deleterious effect on QOL, especially in the physical and emotional domains ⁸.

Despite this, there is a dearth of data from India regarding the relationship between psychotropic-induced ADRs and QOL, particularly in tertiary care public hospitals. The underreporting of ADRs, lack of routine QOL assessments, and limited awareness of pharmacovigilance further aggravate this gap ⁹. Evaluating this relationship is vital to developing patient-centred interventions, optimizing treatment adherence, and enhancing therapeutic outcomes. The present study aims to assess the frequency and profile of ADRs associated with psychotropic medications in a tertiary care psychiatric setup and to evaluate their impact on patients' quality of life using the WHOQOL-BREF tool. This effort underscores the importance of incorporating QOL considerations into pharmacovigilance and clinical decision-making in psychiatric care.

Distribution of Cases According to Age & Gender:

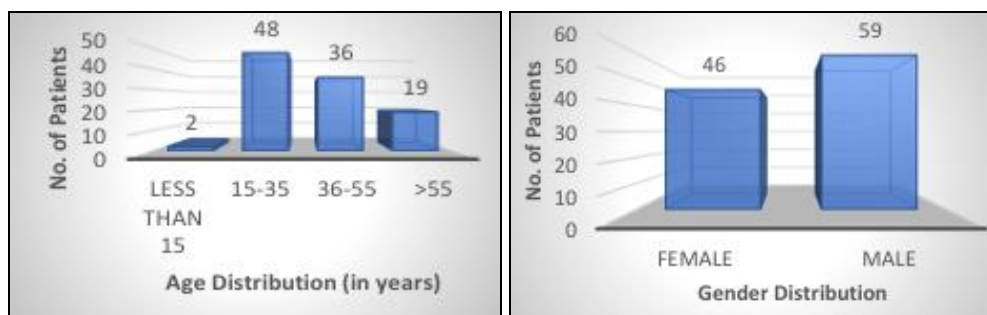


FIG. 1 & FIG. 2: SHOWS THE MEAN AGE OF THE PARTICIPANTS WAS 39.6 YEARS, WITH A MALE PREDOMINANCE (56.2%)

MATERIALS AND METHODS:

Study Design and Site: A cross-sectional observational study conducted at the Department of Psychiatry, JLN Medical College and Hospital, Ajmer, from November 2022 to April 2023.

Inclusion Criteria:

1. Patients of either sex diagnosed with psychiatric disorders as per ICD-10.
2. Receiving one or more psychotropic medications for ≥ 4 weeks.
3. Able to comprehend and consent.

Exclusion Criteria:

1. Cognitive impairment limiting QOL questionnaire completion.
2. Patients on short-term or PRN psychotropic medication.

Tools Used:

1. WHOQOL-BREF Questionnaire (Hindi version)
2. ADR documentation form (PvPI format)
3. WHO-UMC Causality Assessment Scale
4. Hartwig's Severity Assessment Scale

Data Collection & Analysis: QOL was assessed at baseline and at 3-month follow-up. ADRs were recorded and categorized. Statistical analysis was performed using MSO-21 Excel A p-value < 0.05 was considered significant.

RESULTS: Among the 105 psychiatric patients evaluated, 264 ADRs were documented.

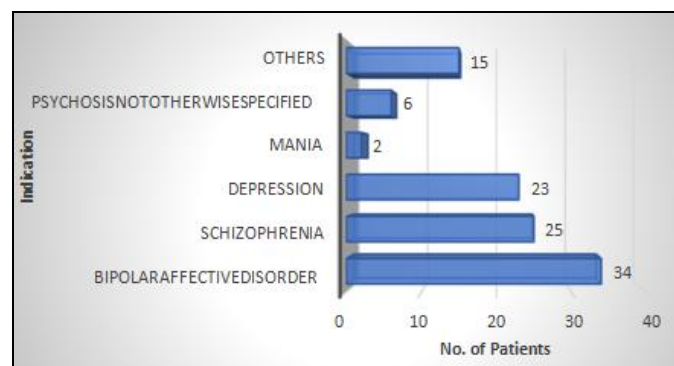
Distribution of Cases According to Indication:

FIG. 3: BIPOLAR AFFECTIVE DISORDER WAS THE MOST PREVALENT DIAGNOSIS (32.4%), FOLLOWED BY SCHIZOPHRENIA AND DEPRESSION

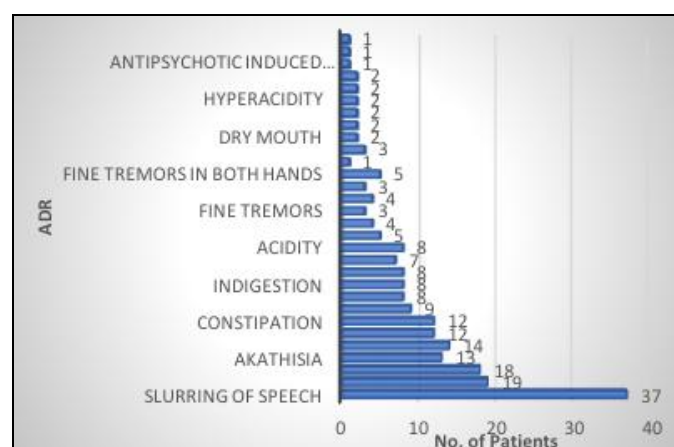
Distribution of Cases According to ADR:

FIG. 4: THE MOST FREQUENTLY REPORTED ADRS WERE SLURRED SPEECH (35.2%), RIGIDITY (18.1%), AND TREMORS (17.1%). OTHER COMMONLY OBSERVED REACTIONS INCLUDED WEIGHT GAIN, AKATHISIA, GASTROINTESTINAL ISSUES (NAUSEA, CONSTIPATION), AND EXCESSIVE SALIVATION

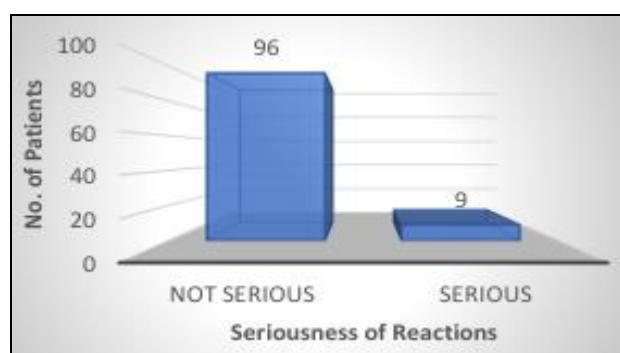
Distribution of Cases According to Intensity of Reaction:

FIG. 5: SEVERITY ASSESSMENT REVEALED THAT 91.4% OF ADRS WERE NON-SERIOUS, WHILE 8.6% WERE CATEGORIZED AS SERIOUS

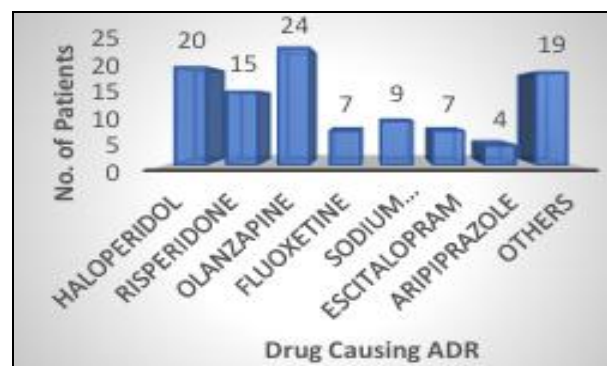
Distribution of Cases According to Drugs:

FIG. 6: AMONG THE DRUGS IMPLICATED, OLANZAPINE (22.8%), HALOPERIDOL (19%), AND RISPERIDONE (14.3%) WERE THE MOST FREQUENT OFFENDERS

WHO-UMC causality assessment showed that most ADRs were probable (54%) or possible (42%). QOL analysis using WHOQOL-BREF indicated a significant decline in physical ($p=0.004$) and psychological ($p=0.008$) domain scores at 3-month follow-up among patients who experienced moderate-to-severe ADRs, particularly those associated with extrapyramidal and sedative side effects. Social and environmental domains showed minimal change, though patients reported perceived limitations in work capacity and mobility. Patients who had no or only mild ADRs maintained stable or improved QOL scores, suggesting a direct link between ADR severity and deterioration in subjective well-being.

DISCUSSION: Our findings reveal that ADRs particularly those induced by antipsychotics have a substantial negative impact on the quality of life of psychiatric patients, especially within the physical and psychological domains. Common ADRs such as extrapyramidal symptoms, sedation, and metabolic disturbances are not only distressing but also interfere with daily functioning, social interaction, and adherence to treatment¹⁰. The observed correlation between ADR severity and diminished QOL highlights the urgent need for proactive ADR monitoring, enhanced patient education, and individualized pharmacotherapeutic strategies¹¹.

Although ADRs were frequent, most were non-serious and preventable. Interventions such as regular clinical monitoring, appropriate dose adjustments, and timely switching to better

tolerated medications can significantly reduce the burden of ADRs. Importantly, integrating routine QOL assessments into psychiatric practice can help identify early signs of treatment related deterioration, enabling pre-emptive measures before significant impairment develops ¹².

This approach is in line with current recommendations from the Indian Pharmacopoeia Commission's PvPI (Pharmacovigilance Programme of India), which advocates for ADR monitoring as an integral component of rational drug use in psychiatry. Furthermore, the World Health Organization emphasizes incorporating QOL instruments like WHOQOL-BREF into mental health programs to holistically evaluate patient well-being and improve treatment outcomes. Our study underscores the necessity of a patient-centric model in psychiatric pharmacotherapy. Linking ADR surveillance with QOL monitoring empowers clinicians to understand the real-world implications of psychotropic medications and make decisions that prioritize both clinical efficacy and the lived experience of patients.

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CONFLICTS OF INTEREST: None declared.

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