



ADVERSE DRUG REACTIONS AND NON-ADHERENCE IN PSYCHOTROPIC THERAPY: IMPLICATIONS FOR CLINICAL PRACTICE

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ABSTRACT

Psychiatric disorders significantly contribute to the global disease burden, necessitating rational use of psychotropic medications for effective management. However, adverse drug reactions (ADRs) remain a critical barrier to medication adherence, potentially compromising treatment outcomes. This pharmacoepidemiological study investigates the patterns of ADRs and their association with non-adherence in psychotropic therapy at a tertiary care teaching hospital in NCR Delhi. Over one year, 300 outpatient prescriptions were analyzed for psychotropic drug utilization, ADR frequency, and adherence patterns using the WHO core prescribing indicators and the Medication Adherence Rating Scale (MARS). Among the study population, 19.7% experienced at least one ADR, predominantly drowsiness (25%) and cogwheel rigidity (17%). Non-adherence was significantly higher among females and patients with comorbidities. Despite a trend toward rational prescribing, polypharmacy (14%) and low generic prescription rates (10%) were observed. Addressing ADR-related non-adherence through patient education, monitoring, and systemic healthcare interventions is crucial for optimizing psychotropic therapy outcomes.

KEYWORDS : Adverse Drug Reactions, Psychotropic Drugs, Medication Adherence, Rational Prescribing.

INTRODUCTION

Psychotropic medications are essential for managing psychiatric disorders, including mood, anxiety, and psychotic disorders. However, the therapeutic success of these medications is often undermined by adverse drug reactions (ADRs) that lead to poor adherence, increased hospitalization rates, and suboptimal clinical outcomes. According to the World Health Organization (WHO), nearly half of all medications are prescribed or used irrationally, exacerbating the risk of ADRs and non adherence.

Pharmacoepidemiology offers a real-world perspective on drug utilization, focusing on prescribing trends, medication safety, and adherence patterns. While research has extensively examined psychotropic drug utilization, fewer studies explore how ADRs influence non-adherence and subsequent clinical outcomes.

This study investigates the prevalence and types of ADRs in psychotropic therapy, their impact on medication adherence, and the implications for clinical practice. By identifying the most common ADRs and patient demographics associated with non-adherence, this research aims to provide actionable insights for improving psychiatric care.

Methods

Study Design and Setting

This hospital-based, observational, prospective study was conducted over one year (December 2022 to December 2023) at the Departments of Psychiatry and Pharmacology, Santosh Medical College & Hospital, a tertiary care center in NCR Delhi. The study aimed to evaluate psychotropic drug utilization patterns, ADRs, and their impact on medication adherence.

Ethical Considerations

Ethical approval was obtained from the Institutional Ethics Committee (IEC) of Santosh University (F. No. SU/2022/3108(19)). Written informed consent was obtained from all participants or their legal representatives. Participants were assured of confidentiality and informed of their right to withdraw at any point without affecting their medical care.

Sample Size and Subject Selection

Using a prevalence-based formula with a 5% allowable error and a confidence interval of 95%, a sample size of 300 patients was determined. Patients were selected through continuous enumeration from the psychiatric outpatient department (OPD).

Inclusion Criteria:

- Adults (≥ 18 years) diagnosed with psychiatric disorders as per ICD-10 criteria.
- Patients prescribed at least one psychotropic medication. First-time treatment seekers for psychiatric illness.
- Willingness to provide informed consent.

Exclusion Criteria:

- Patients with prescription errors or overdose cases.
- Individuals unable to report ADRs or drug-related problems (DRPs).
- Prescriptions not meeting inclusion criteria.

Data Collection

Data were recorded using a structured proforma, including:

- Demographic variables: Age, gender, marital status, employment.
- Clinical variables: Diagnosis, co-morbidities, psychotropic therapy details.
- Adverse Drug Reactions (ADRs): Documented using the WHO-ADR definition and CDSCO reporting forms.
- Medication adherence: Assessed using the Medication Adherence Rating Scale (MARS). Scores of 8–10 indicated adherence, while scores below 7 indicated non-adherence.

Study Protocol

Psychiatric disorders were diagnosed according to ICD-10 classification. Prescribing patterns were evaluated using WHO core prescribing indicators:

- Average number of drugs per prescription.
- Percentage of drugs prescribed by generic names.
- Percentage of drugs from the National List of Essential Medicines (NLEM).
- Frequency of polypharmacy (use of two or more psychotropics).

ADRs were classified by type, severity, and causality. The relationship between ADRs and non-adherence was analyzed to identify significant predictors.

Statistical Analysis

Data analysis was conducted using SPSS version 25. Descriptive statistics summarized demographic and clinical characteristics. The Pearson Chi-square test evaluated the association between demographic variables, ADRs, and medication adherence. A p-value ≤ 0.05 was considered statistically significant.

RESULTS

Socio-Demographic Characteristics

The study included 300 participants from the psychiatric outpatient department. The mean age was 45.67 years (SD: 10.3), with the highest representation in the 41–50 years age group (28%), followed by 31–40 years (25%). Females accounted for 56% of the sample. Over half (59.33%) were married, and a significant proportion (53%) were unemployed.

Table-1

Variable	Frequency (n=300)	Percentage (%)
Age Group (Years)		
18–30	42	14
31–40	75	25
41–50	84	28
51–60	60	20
>60	39	13
Gender		
Male	132	44
Female	168	56
Marital Status		
Married	178	59.33
Single	122	40.67
Employment Status		
Employed	141	47
Unemployed	159	53

Clinical Characteristics and Psychotropic Therapy

- Mood disorders were the most common diagnosis (31.67%), followed by psychotic disorders (24%) and drug dependence (24.33%).
- Monotherapy was the predominant prescription pattern (86%), with polypharmacy in 14% of cases.
- Among co-morbidities, diabetes mellitus was the most prevalent (38.09%), followed by hypertension (27.61%).

Table-2

Psychiatric Disorder	Frequency	Percentage (%)
Mood Disorders	95	31.67
Psychotic Disorders	72	24
Drug Dependence	73	24.33
Anxiety Disorders	55	18.33
Others	5	1.67

Adverse Drug Reactions (ADRs)

A total of 88 ADRs were reported among 19.7% of participants.

- The most common ADRs were drowsiness (25%) and cogwheel rigidity (17%).
- ADRs were most frequently associated with atypical antipsychotics, particularly olanzapine and clozapine.

Table-3

Type of ADR	Frequency (n=88)	Percentage (%)
Drowsiness	22	25
Cogwheel Rigidity	15	17
Tremors	8	9
Weight Gain	11	12.5
Gastrointestinal Issues	9	10.2
Restlessness (Akathisia)	10	11.4
Others	13	14.7

Medication Adherence Patterns

Out of 300 participants, 189 (63%) adhered to their medication regimen, while 111 (37%) were non-adherent.

- Non-adherence was significantly higher among females (46.42%) compared to males (25%), with a p-value of 0.00013.
- Comorbid conditions, unemployment, and polypharmacy were associated with higher non-adherence rates, although statistical significance was limited.

Table-4

Variable	Adhered (n=189)	Not Adhered (n=111)	p Value
Gender			33
Male	99		0.00013
Female	90	78	
Co-morbidities			0.47
Present	69	36	
Absent	120	75	
Employment Status			0.35
Employed	104	55	
Unemployed	85	56	

Drug Utilization Indicators

- Average number of drugs per prescription: 3.09 (WHO standard: 1.6–1.8)
- Generic drug prescriptions: 10% (WHO target: 100%)
- Drugs from NLEM (2022): 70.67%
- Polypharmacy prevalence: 14%

DISCUSSION

The present study highlights the critical interplay between adverse drug reactions (ADRs) and medication non adherence in psychotropic therapy, with significant implications for clinical practice. Despite the essential role of psychotropic medications in managing psychiatric disorders, ADRs remain a major barrier to sustained adherence. This study emphasizes the need for a multifaceted approach that balances efficacy with patient safety.

High ADR Burden and Its Impact on Adherence

A total of 88 ADRs were reported in 19.7% of the study population, with drowsiness (25%) and cogwheel rigidity (17%) being the most common. These findings are consistent with other studies where sedative effects and extrapyramidal symptoms were prevalent side effects of antipsychotic medications. Olanzapine and clozapine were frequently associated with ADRs, reflecting similar trends reported by Sridhar et al., where atypical antipsychotics posed a higher risk of metabolic and neurological side effects.

ADRs, particularly those affecting daily functioning such as drowsiness and weight gain, are known to decrease medication adherence. Patients may discontinue treatment to avoid these discomforts, leading to poor psychiatric outcomes and increased hospitalization rates. In this study, 37% of participants were non-adherent, with higher rates among females and those with comorbidities. Similar gender disparities were observed by Semahegn et al., who found that societal pressures, stigma, and greater perceived side effects contribute to non-adherence among females.

Polypharmacy and Rational Prescribing Challenges

Polypharmacy was observed in 14% of cases, reflecting the complexity of managing psychiatric disorders, particularly in patients with co-morbidities. While combination therapy may be justified in treatment-resistant cases, the risks of drug interactions, higher costs, and increased ADRs must be carefully evaluated.

The WHO recommends limiting the average number of drugs per prescription to 1.6–1.8, whereas this study found a higher average of 3.09, suggesting a need for more rational prescribing. The low rate of generic drug prescriptions (10%) and suboptimal use of the National List of Essential Medicines (NLEM) (70.67%) further indicate areas for improvement. Prior studies, such as Thakkar et al., have echoed similar concerns, emphasizing the economic burden on patients and the need for better alignment with WHO guidelines.

Socioeconomic and Demographic Factors in Non Adherence

Medication adherence is a multifactorial issue influenced by demographic, socioeconomic, and clinical variables.

- Gender: Females demonstrated significantly higher non adherence (46.42%) compared to males (25%), with a p value of 0.00013, indicating a strong association. Cultural and societal factors may play a role, where women prioritize family responsibilities over personal health.
- Comorbidities: Patients with co-morbidities showed slightly higher non-adherence, though not statistically significant. Chronic conditions such as diabetes and hypertension increase the pill burden, contributing to treatment fatigue.
- Employment Status: Unemployment was associated with higher non-adherence (56%) compared to employed individuals (39%). Financial constraints and access to healthcare resources are likely contributing factors.

These findings are consistent with studies by Rekha et al. and Taj et al., which highlight the importance of socioeconomic support in improving adherence rates. Structured follow-ups and personalized interventions addressing economic and psychological barriers are essential for better outcomes.

Strengths and Limitations

The study offers valuable real-world insights into psychotropic drug utilization and adherence patterns.

It emphasizes the underexplored relationship between ADRs and non-adherence, guiding clinical interventions.

The study was conducted in a single tertiary care center, limiting generalizability.

Self-reported adherence through MARS may be subject to reporting bias.

Longitudinal follow-up was not included, which may have provided insights into long-term adherence patterns.

Future studies should aim for multi-center, longitudinal designs to validate findings and explore tailored interventions.

CONCLUSION

This study underscores the significant impact of adverse drug reactions (ADRs) on medication adherence in psychotropic therapy, revealing critical implications for clinical practice. While rational prescribing was evident in many aspects, challenges such as polypharmacy, low generic drug use, and poor adherence remain areas of concern. With 19.7% of participants experiencing at least one ADR and a non-adherence rate of 37%, the findings highlight the need for a balanced approach that prioritizes both efficacy and patient safety.

ADR Burden: Drowsiness, cogwheel rigidity, and weight gain were the most common ADRs, predominantly associated with atypical antipsychotics. **Non-Adherence Factors:** Females, unemployed individuals, and those with comorbidities were at higher risk of non-adherence.

Polypharmacy (14%) and low generic drug prescriptions (10%) suggest a gap in aligning with WHO rational prescribing guidelines.

To enhance treatment outcomes in psychiatric care, the study recommends: **Strengthening Pharmacovigilance:** Routine ADR monitoring and reporting should be integrated into clinical practice. **Tailored patient education and structured follow-ups** are essential for improving adherence. **Promoting Rational Prescribing:** Increasing generic drug prescriptions and minimizing unnecessary polypharmacy can reduce treatment costs and ADRs. **Socioeconomic Support:** Addressing employment-related financial barriers and providing family support systems may improve adherence.

Further multicenter studies with longitudinal follow-ups are warranted to generalize these findings and refine intervention strategies. Optimizing psychotropic drug utilization requires a multidisciplinary approach that incorporates clinical, behavioral, and socioeconomic factors to enhance patient safety and long-term treatment success.

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