Int. J. Pharm. Investigation, 2025; 15(3):926-932.
https://www.jpionline.org

Original Article

Pharmacovigilance of Psychotropics among Patients in A Mental Health Institution of Eastern India

Rakesh Meher[1,*], Roja Sahu[1], Santosh Kumar Ranajit[1], Trupti Rekha Swain[2], Rabinarayan Rana[3], Prafulla Kumar Sahu[1]

[1]Department of Pharmacology, School of Pharmacy, Centurion University of Technology and Management, Bolangir, Odisha, INDIA.
[2]Department of Pharmacology, SCB Medical College and Hospital, Cuttack, Odisha, INDIA.
[3]Department of Pharmacology, Roland Institute of Pharmaceutical Sciences, Berhampur, Odisha, INDIA.

ABSTRACT

Introduction: Polypharmacy, use of narrow therapeutic index drugs and clinical co-morbidities make the patients administered with psychotropics vulnerable to Adverse Drug Reactions (ADRs) and hence, awareness about it is essential for diagnosis and prevention. Objective of this study is to analyze and report ADRs in Mental Health Institution of a tertiary care teaching hospital. **Materials and Methods:** This pharmacovigilance investigation was carried out to report 377 ADRs of 180 psychiatric patients (aged 10-80) administered with psychotropic drugs for duration of 8 months through active surveillance and spontaneous reporting following approval from institutional ethics committee. ADRs were assessed as per their demography along with World Health Organization Uppsala Monitoring Center (WHO UMC) causality assessment, Schumock and Thornton preventability and Modified Hartwig Severity Scale and statistically analyzed by chi-square test. **Results:** ADRs were majorly noticed through active surveillance (64.4%) in male patients (60%) aged 19-29 (32.6%) suffering from Schizophrenia, schizotypal and delusional disorders (37.7%). Majority of the reactions were augmented in nature (68.2%), owing to the pharmacological properties of the psychotropics acting on neurotransmitters. Psychotropics primarily affect the nervous system accounting for 63.9% of ADRs. Antipsychotics were responsible for the highest number of ADRs (59.7%), with tremors observed in 54.6% of patients. Most of ADRs i.e., 53% were classified as 'possible' and 89% ADRs were 'predictable'. In addition, 38% of patients experienced a level 2 severity, indicating less severe nature of psychotropics under use. **Conclusion:** Primary detection of ADRs improves management and reduces useless healthcare expenditure; hence health service providers must take accountability for minimizing ADRs.

Keywords: Adverse drug reaction, Antipsychotics, Pharmacovigilance, Polypharmacy, Psychotropics.

Correspondence:
Mr. Rakesh Meher
Assistant Professor, Department of Pharmacology, School of Pharmacy, Centurion University of Technology and Management, Bolangir-767001, Odisha, INDIA.
Email: rakesh.meher6@gmail.com, rakesh.meher@cutm.ac.in
ORCID: 0000-0002-9340-7306

Received: 18-11-2024;
Revised: 24-01-2025;
Accepted: 07-03-2025.

INTRODUCTION

Adverse Drug Reactions (ADRs) are identified to be a significant cause of sickness and mortality in general hospital setup ranging from 0.2% to 41.3%, most of which are preventable (Hakkarainen *et al.*, 2012). ADRs, often resulting from inadequate medication compliance, can lower life quality due to societal stigma, leading to physical morbidity (Haddad & Sharma, 2007). This underscores the need for their scrutiny, tracking and control. Monitoring of ADRs in a hospital setting allows identification of high-risk patients and supports in understanding their nature and incidence in general population (Polard, 2016), which will assist in building an appropriate strategy to manage, prevent and minimize the risk of developing ADRs, thereby reducing the healthcare expenditure (Rajakannan *et al.*, 2012). Scientific tools like pharmacovigilance study can provide assistance in this regard by assessing the adverse effects of medications over both shorter and longer durations (Singh *et al.*, 2017).

Research indicates that psychotropic medications such as antipsychotics and mood stabilizers are known to instigate ADRs very frequently even at their therapeutic doses (Sengupta *et al.*, 2011). Most patients suffering from psychiatric illness need long-term therapy with psychotropic medication which makes them vulnerable to ADRs (Arawal, 2015), which include weight gain, drowsiness, tremors and tardive dyskinesia. A majority of ADRs occurs frequently due to shift in pharmacodynamic and pharmacokinetic parameters, enhanced reactive drug metabolites levels, Drug-Drug Interaction (DDI) and their impaired detoxification (Alomar, 2014). Polypharmacy, use of medications having narrow therapeutic index and presence of clinical co-morbidities are the basic factor which makes the psychiatric

DOI: 10.5530/ijpi.20250235

patients vulnerable to ADRs (Lavan and Gallaghher, 2016). Monitoring of ADRs in psychiatry units can play a crucial role in recognizing and alerting doctors about the possibility of such reaction, thereby protecting the patients from avoidable damage (Sengupta *et al.*, 2011). Moreover, in India, the pharmacovigilance studies need to be strengthened with adequate data related to ADRs, especially with psychotropic drugs (Shah and Mehta, 2014).

There is no data available on the ADRs of psychotropic drugs in psychiatry patient in mental health institutions, indicating limited research done in this spectrum till date. Taking this view in mind, this study aims to find out the pattern of ADRs of psychotropics used in the department of psychiatry in both ambulatory and hospitalized patients. Pharmacovigilance of psychotropic medication was examined by measuring the frequency, pattern, predictability, preventability and severity of ADRs. Furthermore, the indicator and pattern of ADRs were evaluated along with creating awareness in all health service providers and patients.

MATERIALS AND METHODS

Participants

This study was conducted in the Department of Psychiatry, Mental Health Institute (MHI), Srirama Chandra Bhanja Medical College and Hospital (SCBMCH), Cuttack, Odisha, India over a period of eight months. Before initiating the investigation, approval was received from the Institutional Ethical Committee (IEC No 154/2020 dated 07.02.2020, 36th meeting). The study ensured the preservation of patient information confidentiality and anonymity at every stage of the research.

As per International Classification of Disease (10th revision) Diagnostic Criteria for Research (ICD-10 DCR), patients aged 10-80 diagnosed with any psychiatric disorder (Castagnini and Galeazzi, 2016), whom treated with at least one psychotropic medication from either IPD or OPD were taken into consideration for this study. Exclusion criteria involved patients exhibiting aggressive and violent behavior and patients with physical comorbidities such as head injuries and self-injuries like wrist cutting etc. In addition, patients receiving medication other than psychotropics as well as psychotropic medication other than allopathic were excluded too from the analysis.

Data collection

Data are collected through various sources like history sheets, clinical notes, nursing notes, etc. Discussions with patients, caregivers and healthcare staff further enriched our data collection. Data collection form is used to collect the patient's particular, socio-demographic factors like age and gender, clinical data according to ICD 10th revision disease condition, past medical history, the reason for admission, diagnosis, drug used, adverse drug reaction and its management.

An ADR evaluation form was developed in line with the guidelines of the Indian Pharmacopeia Commission (Rajpara and Kanani, 2019). This form includes details of the suspected adverse drug reaction, such as a concise description of the reaction, its nature, the date it started, the treatment provided and the outcome. It also outlines the complete dosage regimen of the suspected drug(s). The form encompasses various parameters related to causality categories, severity grading, predictability and preventability, based on several standard scales used in ADR assessment. Furthermore, it is designed to incorporate other necessary details about ADR, such as the type of ADR, reporting method and the time taken for ADR detection. This is a prospective study that concurrently used active surveillance pharmacovigilance methodology and spontaneous reporting. All the patients were followed regularly within a time interval of 7 days up to 3 months for the documentation and citations of both short-term and long-term ADRs. ADRs were recognized utilizing both objective markers (e.g. weight and blood pressure measures, pathological lab results) and subjective markers (e.g. headache, abdominal pain, nausea). The patients were instructed to contact the investigation pharmacist if any new symptoms appeared or if any new medication started during the follow-up period.

Assessment Tools

Various tools were employed to measure the causality, predictability, preventability and severity of ADRs. Causality assessment was done to identify the underlying link between the suspected drug and the response through WHO-ADR causality indicators (Esteves *et al.*, 2021), categorized as "conditional/ unclassified, unlikely, unassessable/unclassifiable, probable and certain" by employing WHO-UMC System to Conduct Standardized Case Causality assessment. Royer's scale is a system to measure the predictability of the ADRs that characterized the ADRs as type A (dose-dependent and predictable), type B (peculiar, unpredictable and dose-independent), type C (chronic) and type D (delayed reactions) (Meyboom and Royer, 1992). Further, each ADR's preventability was examined using a modified Schumock and Thornton scale and classified as certainly preventable, possibly preventable, or not preventable (Misra *et al.*, 2013). The severity of reported responses was graded using the Hartwig and Siegel scale and classified from Level 1 to Level 7 (Hartwig *et al.*, 1992).

Statistical Analysis

The data were sorted, coded and entered into Statistical Package for the Social Science (SPSS) Windows Version 22 and analyzed subsequently. WHO-UMC Scale, Predictability, preventability and severity scale were expressed as mean and standard deviation. Statistical significance was determined using Pearson's chi square test at 95% level of confidence interval ($p<0.05$). The variables tested for identification of predictors were category of

hospitalized patient, gender, age, number of medications, past psychiatry illness and disease categories.

RESULTS

In this examination, patients were categorized based on their admission, gender, age, number of medications and past psychiatric illness (Table 1). Out of 377 ADRs analyzed in this investigation, 132 were recognized to be from 62 IPD patients while 245 were from 118 OPD patients. Male patients displayed more ADRs i.e., 58.4% as compared to females (41.6%). In addition, the age group of 19-29 showed about one third of the ADRs i.e., 32.6%. Furthermore, occurrence of ADRs resulted in a hospital stay extension in 12 hospitalized cases. A maximum of six ADRs were exhibited by a single patient which were recorded at various intervals throughout her 15-day hospital stay. Approximately 51.2% patient taking more than one medication at a time exhibited ADRs indicating key role of polypharmacy in it. Further, the patients having a history of psychiatric illness are prone to exhibit ADRs as compared to the ones without any history.

In this article, the majority of the ADRs were reported by active surveillance by directly interacting with patients. Out of the 395 ADRs reported from 191 patients, 377 ADRs from 180 patients were considered for the study and 18 ADRs from 11 patients were excluded due to the lack of data. From the included patient, 116 (64.4%) were noticed by active surveillance, while remaining 35.6% were spontaneously reported by the patient, caregivers, or healthcare staff throughout the study period of 8 months. The amount of spontaneous reporting was gradually increased from an initial 2.6% to 24.1% by the end of the study (Figure 1).

According to ICD-10 guidelines, the incidence of ADRs categorized in different classes i.e., F01 to F99 and G21 to G40 was arranged in Table 2. According to our survey, maximum i.e., 37.7% ADRs were reported by patients suffering from Schizophrenia, schizotypal and delusional disorders (F20-F29), whereas minimum no. of ADRs (1.3%) were observed in patients having behavioral and emotional problems with onset typically in childhood and adolescence (F90-F99).

All the reported ADRs were classified as per the Royer's characterization scale into either Type A, Type B, Type C, or Type D (Table 3). Majority of the reactions were augmented in nature i.e., 68.2%, owing to the pharmacological properties of the psychotropic medication that acts on various neurotransmitters. As psychiatric disorders are chronic disorders requiring long term medication, 25.7% ADRs belongs to Type-C category which is secondary to type A reactions. Moreover, in few cases, acne, tinnitus like type B (Bizarre) reactions were observed.

Detailed report of ADRs of the individual medications (Supplementary Table 1) showcased that, nervous system (CNS and PNS) (63.9%) is the most commonly impacted organ system by ADRs due to the use of psychotropics followed by the gastrointestinal system (GI) (14%). Most common ADR reported was tremor (*n*=206), followed by akathisia (*n*=91), slurring of speech (*n*=52) and hypersalivation (*n*=49). Administration of antipsychotics [*n*=225 (59.7%)] are frequently associated

Table 1: Categorization of adverse drug reaction according to Patient Demographic data.

	Characteristics	No. of patients with ADR	No. of ADRs	Sig. (2-tailed)
Category	IPD	62(34.4%)	132(35%)	0.007
	OPD	118(65.5%)	245(65%)	
Gender	Male	108(60%)	220(58.4%)	0.007
	Female	72(40%)	157(41.6%)	
Age	<19	17(9.4%)	33(8.8%)	0.087
	19-29	57(31.7%)	123(32.6%)	
	30-39	42(23.3%)	93(24.7%)	
	40-49	28(15.6%)	53(14.1%)	
	50-59	25(13.9%)	54(14.3%)	
	≥60	11(6.1%)	21(5.6%)	
Number of medications	One	1(0.6%)	3(0.8%)	0.090
	Two	98(54.4%)	193(51.2%)	
	Three	69(38.3%)	149(39.5%)	
	More than four	12(6.7%)	32(8.5%)	
Past psychiatric illness	Absent	104(57.8)	213(56.5%)	0.017
	Present	76(42.2)	164(43.5%)	

*Based on Pearson's chi square test, the correlation is significant at the 0.05 level (2-tailed).

with ADRs followed by mood stabilizer [*n*=115 (30.5%)] and antidepressant [*n*=29 (7.7%)]. The first-generation typical antipsychotic drug, haloperidol (*n*=162) is most vulnerable to ADRs followed by olanzapine (*n*=125), valproate (*n*=112) and risperidone(*n*=92). Additionally, tremor (*n*=55), akathisia (*n*=28) and slurring of speech (*n*=13) etc. were typically observed with both haloperidol and olanzapine. Moreover, out of 377 ADRs, short-term and long-term ADRs constitute nearly 67% and 33% respectively. Commonly observed short-term ADR includes tremor, akathisia, hypersalivation whereas the long-term ADR are tremor, akathisia and slurring of speech.

WHO-UMC probability scale was employed to analyze the level of causality as denoted in Figure 2 (A), where we observed that majority of the ADRs belonged to 'possible' (*n*=200), some belonged to 'probable'(*n*=96) and a small number were found to be in 'certain'(*n*=5) category. Predictability measurement done through Royer's characterization depicted that, a total of 334 numbers of ADRs (89%) were predictable. This may be because most of the reactions were exacerbations of pharmacological actions of the drugs that act on various neurotransmitters and receptors. Of the 377 reported ADRs, 40% were classified as definitely preventable, 43% as probably preventable and 17% as not preventable (Figure 2 (B)). The severity of reported reactions was classified using the Hartwig and Siegel scale from Level 1 to Level 7 as represented in Figure 2 (C), where highest number of patients (38%) were on severity level-2 and only 2% patients suffered from level 5 severity. Furthermore, statistical analysis of various parameters was assessed in 180 patients as denoted in Table 4.

DISCUSSION

Since, drugs are the double-edged weapon with potential benefit and harm, hence, the purpose of our initiative was to ensure that the assistance of medicine outweigh the risks, maximize clinical

Table 2: Categorization of adverse drug reactions according to International Classification of Disease (10th revision).

Disease Category	Number of Patient	Number of ADRs	Sig. (2-tailed)
F01-F09	17(9.4%)	31(8.2%)	0.028
F10-F19	3(1.7%)	7(1.9%)	
F20-F29	72(40.0%)	142(37.7%)	
F30-F39	49(27.2%)	105(27.9%)	
F40-F49	2(1.1%)	7(1.9%)	
F50-F59	26(14.4%)	59(15.7%)	
F60-F69	0	0	
F70-F79	3(1.7%)	5(1.3%)	
F80-F89	0	0	
F90-F99	3(1.7%)	5(1.3%)	
G21-G40	5(2.8%)	16(4.2%)	

*Based on Pearson's chi square test, the correlation is significant at the 0.05 level (2-tailed).(F01-F09=Organic, includes symptoms, mental disorders and infections) F10-F19=Mental and behavioral problems caused by the use of psychoactive substances, F20-F29=Schizophrenia, as well as schizotypal and delusional illnesses. Mood [affective] disorders F30-F39 Neurotic, stress-related and somatoform disorders F40-F49 F50-F59 = Behavioral disorders linked to physiological abnormalities and physical factors F60-F69=Adult personality and behavior disorders, F70-F79=Mental retardation, F80-F89=Psychological development disorders G21-G40=Epilepsy, parkinsonism and Alzheimer's disease, F90-F99=Behavioral and emotional problems with onset typically in childhood and adolescence).

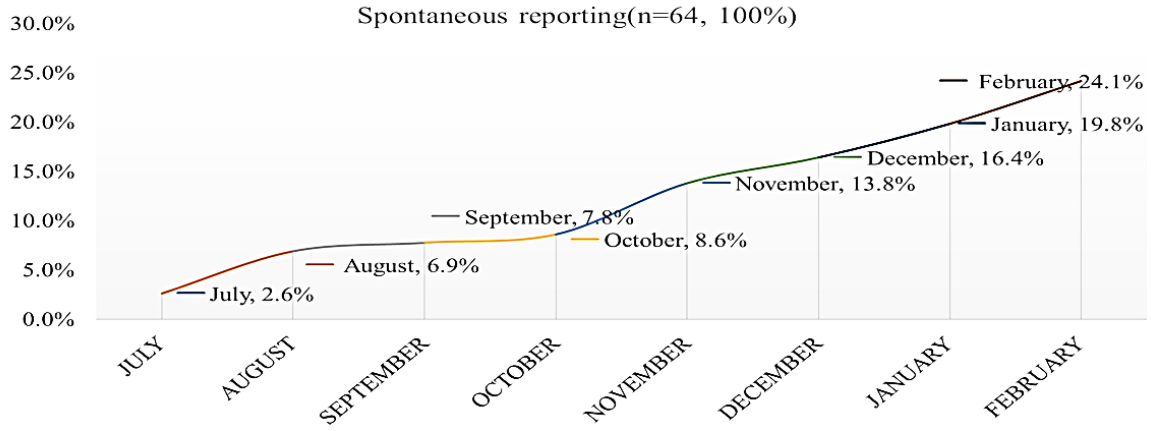

Figure 1: Trends of spontaneous reporting of adverse drug reaction from the month of July 2019 to February 2020.

effectiveness, minimize ADRs and provide cost-saving treatment. Pharmacovigilance is the program conducted worldwide to report various adverse reactions occurring due to drugs that are already being marketed. Present study reported ADR cases from mental health unit of (the SCB medical college and hospital for a duration of eight months to provide an insight of the ADRs associated with the psychotropic drugs currently being used in the locality.

As per our findings, majority of ADRs were reported by active surveillance (64.4%) as compared to previous Indian researches (35.6%) (Farcas *et al.*, 2010; Scavone *et al.*, 2020), which may attribute to the highly established ADR monitoring and reporting system in the research location. Further, involvement of clinical pharmacists in the psychiatric department may have a role in improving the spontaneous reporting rate to almost 9 times (2.6% to 24.1%) (Francis *et al.*, 2015). Health Care Professionals (HCPs), particularly psychiatrists had reported the ADRs spontaneously which is limited to moderate to severe and infrequent responses. This discovery contrasts Jose *et al.* suggesting frequent reporting of mild to moderate and common reactions (Francis *et al.*, 2015). The disparity may be because of the differences in the knowledge, attitude and practice of the clinicians (Venkatasubbaiah *et al.*, 2018). Other likely reasons for underreporting include improper knowledge of doctors regarding reporting of ADRs to Pharmacovigilance centers, lack of time, unavailability of ADRs reporting forms, lack of acknowledgement letters or credits and so on (Venkatasubbaiah *et al.*, 2018).

The incidence of ADRs in the OPD patient was higher than IPD patient. In addition, we found an elevated incidence of ADRs among males which is in contrast to previous researches conveying more common reporting of ADRs in females (D'Incau P *et al.*, 2014). The age group of 19-29 exhibited maximum ADRs resulting from polypharmacy. All reported ADRs were known

Table 3: Types with Number of Adverse drug Reaction.

Types of Reaction	No. of ADRs
Type-A (Augmented)	257(68.2%)
Type-B (Bizarre)	13(3.4%)
Type-C (Chronic)	97(25.7%)
Type-D (Delayed)	10(2.7%)
Total	377(100%)

Table 4: Assessment Scale with Standard deviation.

Scale	N	Minimum	Maximum	Mean	Std. Deviation
WHO-UMC Assessment	180	0	2	0.46	0.553
Predictability Scale	180	1	2	1.92	0.269
Schumock and Thronton Preventability Scale	180	0	2	0.53	0.672
Hartwig Severity scale	180	1	5	2.25	0.980

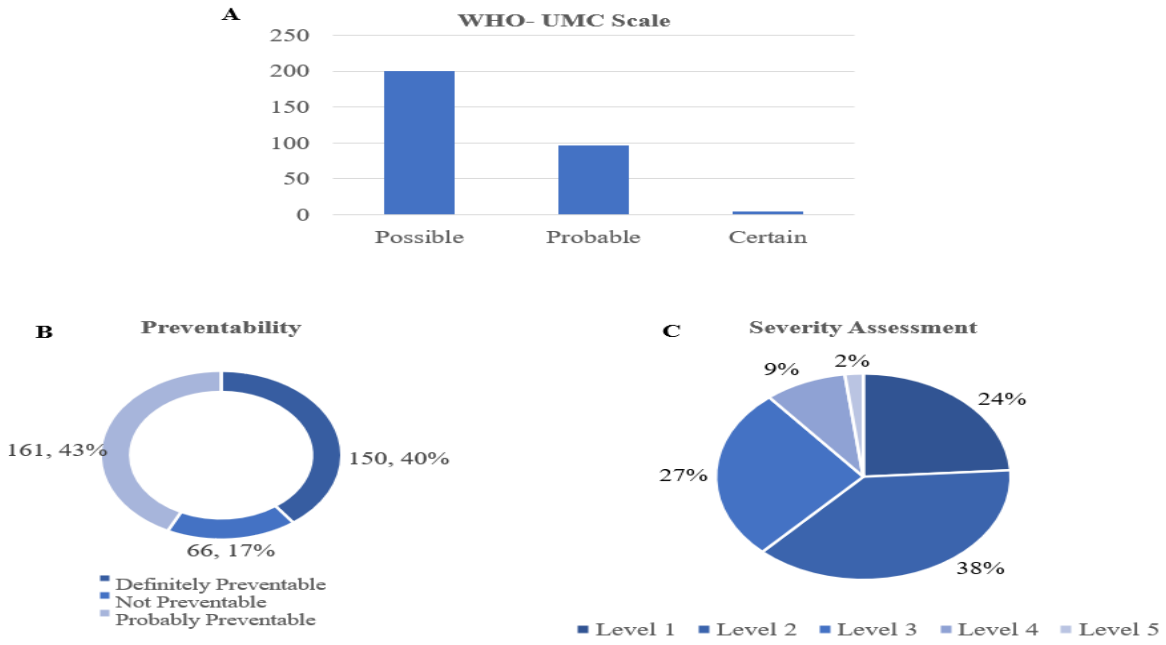

Figure 2: (A) Number of adverse drug reactions assessed through World Health Organization - Uppsala monitoring center; (B) Number and percentage of adverse drug reaction assessed using modified Schumock and Thornton preventability scale; (C) Percentage of adverse drug reaction assessed using the Hartwig and Siegel severity scale.

medication responses with no new observations. As per the Royer's characterization scale most of the ADRs are found to be of Type-A category i.e., dose-dependent and predictable, which is not surprising and in consistent with the previous studies (Gor and Desai, 2008). Furthermore, withdrawal of drugs associated with a particular ADR can prevent the event; however, the data obtained in our study is insufficient to explain it.

Antipsychotics are the prime reason for ADRs (59.7%), followed by mood stabilizers (30.5%) and antidepressants (7.7%) i.e., in consistent with the finding of previous researchers (Gor and Desai, 2008; Piparva *et al*., 2011; Cassano and Fava, 2004). Nervous system was observed to be the frequently impacted organ due to the ADRs caused by psychotropics followed by gastrointestinal system in our study, which contradicts the previous discoveries suggesting gastrointestinal system as the predominant organ system affected by ADRs (Shah and Mehta, 2014). Tremor, akathisia, slurring of speech and hypersalivation were the most frequently reported ADRs, since, psychotropic agents are known to act on serotonergic, dopaminergic, adrenergic, histaminergic, glutaminergic and anticholinergic receptors.

In spite of publication of numerous diagnostic criteria for studying the ADRs associated causality assessments, still there is a lack to examine the inter- and intra-rater variance. WHO UMC's method for causality assessment is an easy, extensively used and broadly recognized method. In this assessment we have found that, only 5 patients out of 180 which is supposed to Certain categories, which is in contrast to the findings of Verma *et al*. reporting nearly 30% ADRs in this category (Kushwaha *et al*., 2022). Generally, pharmacological action of a drug aggravated majority of the reaction, causing nearly 85% of ADRs predictable in our findings. Only a few patients had any documented ADRs or allergy history of suspected drug. Drugs majorly linked with avoidable ADRs is found to be Antipsychotics in our research. Further, degree of preventability depends on the variations of the patient's profile in different study settings. In the majority of the preventable ADRs, patients did not receive prescriptions for administration of preventive measures. A considerable number of ADRs were result from polypharmacy and hence, can be preventable.

CONCLUSION

ADRs has a significant limitation to the success of therapeutics. Early discovery and inhibition of potential ADRs may bring about better therapeutic results and diminished pointless healthcare expenses. The United States' Health Information Technology for Economic and Clinical Health Act assigns hospitals access to computerized physician order input and electronic health records. It has claimed to minimize patient grievances by 50% resulting from pharmaceutical mistakes along with ADRs. Likewise, the finding of our study indicates the prescription of lesser number of medications will minimize ADRs associated with polypharmacy. Administration of adjuvant drugs will lower the predictable and preventable ADRs. However, it had issues with drug-drug interaction and drug-food interactions, difficulties in causality assessment due to ethical concerns and unknown recovery in some cases due to follow-up difficulties and thus, requiring follow-up for further evaluation.

ACKNOWLEDGEMENT

The authors are thankful to Srirama Chandra Bhanja Medical College and Hospital for their kind of help and support in the research work.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

ADRs: Adverse Drug Reactions; **WHO-UMC:** World Health Organization Uppsala Monitoring Center; **DDI:** Drug-Drug Interaction; **MHI:** Mental Health Institute; **SPSS:** Statistical Package for the Social Science; **GI:** Gastro Intestinal; **OPD:** Out Patient Department; **IPD:** In Patient Department; **HCPs:** Healthcare Professionals.

ETHICAL APPROVAL

Approval from SCB Medical college and Hospital bearing IEC No 154/2020 dated 07.02.2020, 36th meeting.

AUTHOR CONTRIBUTIONS

Rakesh Meher: Conceptualization, Methodology, Software, manuscript writing; Roja Sahu: Data curation, Writing-Original draft preparation, Reviewing and Editing; Santosh Kumar Ranajit: Visualization, Investigation; Trupti Rekha Swain: Supervision; Rabinarayan Rana: Visualization, Investigation; Prafulla Kumar Sahu: Reviewing and Editing.

REFERENCES

Agrawal, P. (2015). A focus on medication error. J. Pharmacovigil, s2

Alomar, M. J. (2014) Apr. Factors affecting the development of adverse drug reactions (Review article). Saudi Pharmaceutical Journal, 22(2), 83–94. https://doi.org/10.1016/j.jsps.2013.02.003

Cassano, P., & Fava, M. (2004). Tolerability issues during long-term treatment with antidepressants. Annals of Clinical Psychiatry, 16(1), 15–25. https://doi.org/10.1080/10401230490281618

Castagnini, A., & Galeazzi, G. M. (2016). Acute and transient psychoses: Clinical and Nosological issues. BJPsych Advances, 22(5), 292–300. https://doi.org/10.1192/apt.bp.115.015198

D'Incau, P., Lapeyre-Mestre, M., Carvajal, A., Donati, M., Salado, I., Rodriguez, L., Sáinz, M., Escudero, A., & Conforti, A. (2014). No differences between men and women in adverse drug reactions related to psychotropic drugs: A survey from F rance, I taly and S pain. Fundamental and Clinical Pharmacology, 28(3), 342–348. https://doi.org/10.1111/fcp.12032

Esteves, A., Teixeira da Silva, F., Carvalho, J., Carvoeiro, A., & Felgueiras, P. (2021, January 25). Diclofenac-induced immune hemolytic anemia: A case report and review of literature. Cureus, 13(1), Article e12903. https://doi.org/10.7759/cureus.12903

Farcas, A., Sinpetrean, A., Mogosan, C., Palage, M., Vostinaru, O., Bojita, M., & Dumitrascu, D. (2010). Adverse drug reactions detected by stimulated spontaneous reporting in

an internal medicine department in Romania. European Journal of Internal Medicine, 21(5), 453–457. https://doi.org/10.1016/j.ejim.2010.05.014

Francis, J., Palaniappan, M., Dubashi, B., Pradhan, S. C., & Chandrasekaran, A. (2015). Adverse drug reactions of imatinib in patients with chronic myeloid leukemia: A single-center surveillance study. Journal of Pharmacology and Pharmacotherapeutics, 6(1), 30–33. https://doi.org/10.4103/0976-500X.149141

Gor, A. P., & Desai, S. V. (2008, January). Adverse drug reactions (ADR) in the in Patients of medicine department of a rural tertiary care teaching hospital and influence of pharmacovigilance in reporting ADR. Indian Journal of Pharmacology, 40(1), 37–40. https://doi.org/10.4103/0253-7613.40488

Haddad, P. M., & Sharma, S. G. (2007). Adverse effects of atypical antipsychotics: Differential risk and clinical implications. CNS Drugs, 21(11), 911–936. https://doi.org/10.2165/00023210-200721110-00004

Hakkarainen, K. M., Hedna, K., Petzold, M., & Hägg, S. (2012, March 15). Percentage of patients with preventable adverse drug reactions and preventability of adverse drug reactions—A meta-analysis. PLOS One, 7(3), Article e33236. https://doi.org/10.1371/journal.pone.0033236

Harichandran, D., Viswanathan, M., & Gangadhar, R. (2016). Adverse drug reactions among hospitalized patients in Psychiatry Department in a Tertiary Care Hospital. Journal of Health Research and Reviews, 3(2), 77. https://doi.org/10.4103/2394-2010.184243

Hartwig, S. C., Siegel, J., & Schneider, P. J. (1992). Preventability and severity assessment in reporting adverse drug reactions. American Journal of Hospital Pharmacy, 49(9), 2229–2232. https://doi.org/10.1093/ajhp/49.9.2229

Kushwaha, V., Agrawal, P., Singh, S., Chaudhary, D., Verma, A. K., & Sharma, H. (2022). Assessment of adverse drug reactions of antidepressant drugs used in psychiatry department of A tertiary Care Hospital. Asian Journal of Pharmaceutical and Clinical Research, 49–54. https://doi.org/10.22159/ajpcr.2022.v15i4.44287

Lavan, A. H., & Gallagher, P. (2016, February). Predicting risk of adverse drug reactions in older adults. Therapeutic Advances in Drug Safety, 7(1), 11–22. https://doi.org/10.1177/2042098615615472

Meyboom, R. H. B., & Royer, R. J. (1992). Causality classification at pharmacovigilance centres in the European Community. Pharmacoepidemiology and Drug Safety, 1(2), 87–97. https://doi.org/10.1002/pds.2630010207

Mishra, S., Swain, T. R., & Mohanty, M. (2013, June 01). Adverse drug reaction monitoring of antidepressants in the psychiatry outpatients department of a tertiary care teaching hospital. Journal of Clinical and Diagnostic Research, 7(6), 1131–1134. https://doi.org/10.7860/JCDR/2013/4985.3041

Piparva, K. G., Buch, J. G., & Chandrani, K. V. (2011, July). Analysis of adverse drug reactions of atypical antipsychotic drugs in psychiatry OPD. Indian Journal of Psychological Medicine, 33(2), 153–157. https://doi.org/10.4103/0253-7176.92067

Polard, E. (2016). Pharmacovigilance – Surveillance du risque médicamenteux. Médicaments et Produits Pharmaceutiques. https://doi.org/10.51257/a-v1-pha3060

Rajakannan, T., Mallayasamy, S., Guddattu, V., Kamath, A., Vilakkthala, R., Rao, P. G. M., & Bairy, L. K. (2012). Cost of adverse drug reactions in a south Indian tertiary care teaching hospital. Journal of Clinical Pharmacology, 52(4), 559–565. https://doi.org/10.1177/0091270011398867

Rajpara, A., & Kanani, N. (2019). An intensive monitoring of adverse drug reaction in indoor patients of medicine department at tertiary care teaching hospital: A single center, prospective and multisource observational study. National Journal of Physiology, Pharmacy and Pharmacology, 0, 1. https://doi.org/10.5455/njppp.2019.9.0516616052019

Scavone, C., Mascolo, A., Ruggiero, R., Sportiello, L., Rafaniello, C., Berrino, L., & Capuano, A. (2020, April 15). Quinolones-induced musculoskeletal, neurological and psychiatric ADRs: A pharmacovigilance study based on data from the Italian spontaneous reporting system. Frontiers in Pharmacology, 11, 428. https://doi.org/10.3389/fphar.2020.00428

SenGupta, G., Bhowmick, S., Hazra, A., Datta, A., & Rahaman, M. (2011, February). Adverse drug reaction monitoring in psychiatry out-patient department of an Indian teaching hospital. Indian Journal of Pharmacology, 43(1), 36–39. https://doi.org/10.4103/0253-7613.75664

Shah, V. M., & Mehta, D. S. (2014). A longitudinal study of monitoring adverse drug reactions at psychiatry out-patient-department in our tertiary care teaching hospital, Surendranagar. Journal of Drug Delivery and Therapeutics, 4(1). https://doi.org/10.22270/jddt.v4i1.738

Singh, H., Yacob, M., Sabu, L., & K, M. (2017). Adverse drug reactions monitoring of psychotropic drugs: A tertiary care centre study. Open Journal of Psychiatry and Allied Sciences, 8(2), 136. https://doi.org/10.5958/2394-2061.2017.00009.X

Venkatasubbaiah, M., Dwarakanadha Reddy, P., & Satyanarayana, S. V. (2018). Analysis and reporting of adverse drug reactions at a tertiary care teaching hospital. Alexandria Journal of Medicine, 54(4), 597–603. https://doi.org/10.1016/j.ajme.2018.10.005

Cite this article: Meher R, Sahu R, Ranajit SK, Swain TR, Rana R, Sahu PK. Pharmacovigilance of Psychotropics among Patients in A Mental Health Institution of Eastern India. Int. J. Pharm. Investigation. 2025;15(3):926-32.