MONITORING, REPORTING AND MANAGEMENT OF ADVERSE DRUG REACTIONS IN PSYCHIATRIC WARD OF A TERTIARY CARE HOSPITAL

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ABSTRACT

Background*: Adverse drug reactions (ADRs) to psychotropic agents are common and can lead to noncompliance or even discontinuation of therapy. Most of the data available on adverse drug events addresses to patients of out setting departments, surgery wards, medicine wards and every few towards psychiatric in-patients; where the patient's life is on continuous alteration of doses and outcome of which at times is seen as an adverse event.*

Objective*: Monitoring, reporting and management of adverse drug reactions in psychiatric department (That includes suspecting and categorization of ADR). Evaluation of the incidence rate for patients with ADR's. Measuring the severity, preventability and resolution of ADR's have to be detected.*

Methodology*: It is a prospective observational study that will be carried out in the psychiatric department of a tertiary care institution. After explaining the study to the participants, informed consent was obtained.*

Results*: The present study includes 200 patients fulfilling the inclusion criteria. Among these 200 patients they were again categorized in two category with ADRs and without ADRs. This study's 19.5% incidence rate of ADRs was found to be comparable to that in other trials, where it ranged from 3.6% to 91%. A total of 39 ADRs were detected.*

Conclusion*: The goal of the current study was to monitor and report un favourable events that occur in a tertiary care hospital's mental unit. The submitted evidenced ADRs were handled for additional review after being reported.*

Keywords: Adverse drug reaction, Psychiatry department, WHO probability scale

INTRODUCTION

The medical field of psychiatry is focused on the identification, avoidance, analysis, and treatment of "mental diseases."[1] These include diverse mood, behavior, cognition, and perception-related mal adaptations.

Only trained professionals with keen observation skills are able to spot an ADR. Case reports are the most crucial resource for observational research. Patients who take new medications run the risk of developing adverse drug reactions. ADRs are frequently mistaken for signs of underlying disorders or diseases. Therefore, having a thorough understanding of the pharmacology of the medications is crucial.

The method of continuously monitoring unfavourable effects thought to be related to the use of pharmaceuticals is known as adverse drug reaction monitoring. By anticipating probable ADRs that can be prevented, the pharmacist has the chance to significantly influence patient care. ADR monitoring was first conducted in India in 1982, under the direction of the country's drug controller general.

When an ADR is suspected, it may be beneficial to determine whether the medicine is certainly, probably, or potentially to blame for the reaction. The evaluation of causation is the process in question. In an effort to justify causality assessment of adverse reactions, numerous systematic methodologies or algorithms have been created.

It contains the WHO probability scale, the Naranjo's ADR probability scale, the Karch and Lasagna causation assessment scale, the Modified Hartwig and Siegel ADR severity assessment scale, and the criteria for judging predictability of an ADR (Modified Shumock and Thornton).

Proper information regarding the safety of pharmaceuticals and treatments is one of the advantages of ADR monitoring. protection against side effects caused by medicinal drugs, and Instruction on ADRs and their management for the medical staff, patients, pharmacists, and nurses.

Role of Clinical Pharmacist in Monitoring and Reporting of ADRs

The development of policies and procedures for the monitoring and reporting of ADRs, the explanation of the roles and responsibilities of drugs by the pharmacist, nurses, risk managers, and other healthcare professionals in the ADR programme, and education of other healthcare professionals about prevention, detection, and reporting of ADRs are all necessary. Identifying the medications and patients who are most likely to experience adverse drug reactions (ADRs), reporting serious ADRs to the FDA, and providing patient education regarding ADRs.

METHOD

Study design and study period

In a tertiary care hospital's inpatient and outpatient department of psychology, a prospective observational study was carried out. The investigation lasted for six months.

Source of data

Data was gathered from treatment records and during interviews with study of participants at the O.P. and I.P. departments about their medication histories. The following scales were used to assess ADRs: Patient treatment chart, Rawlins and Thomson classification of ADRs Modified Hart wig and Siegel severity scale, Shomuck and Thornton preventability scale. All subject recruitment in the psychiatry outpatient and inpatient departments was vetted.

Method of collection of data

It is a prospective observational study that will be carried out in the psychiatric department of a tertiary care institution. After explaining the study to the participants, informed consent was obtained.

Statistical analysis

A Microsoft Excel spread sheet was used to record all information about the recruited subjects. Patient demographic factors were calculated using descriptive statistics. 200 patients that meet the inclusion criteria are included in the current study. These 200 patients were once more divided into two categories: those with and those without adverse drug reactions.

RESULTS

1. Gender wise distribution of ADRs

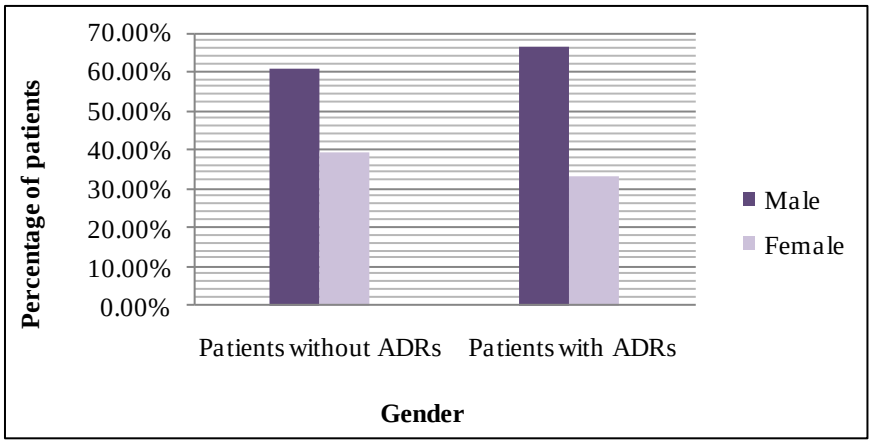

Fig.1: Gender wise distribution of ADRs

2. Age wise distribution of ADRs

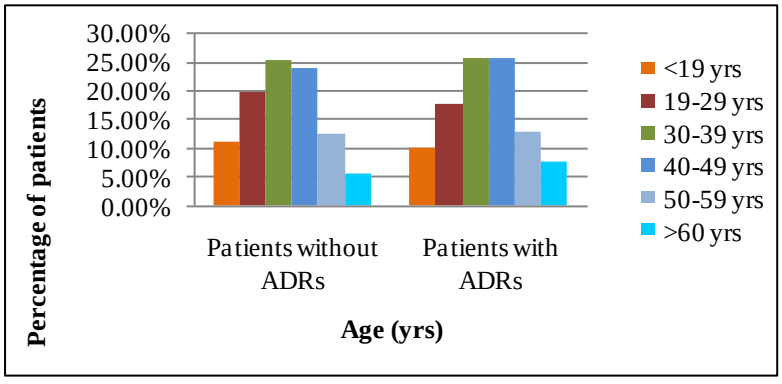

Fig.2: Age wise distribution of ADRs

3. Inpatient & Outpatient data distribution

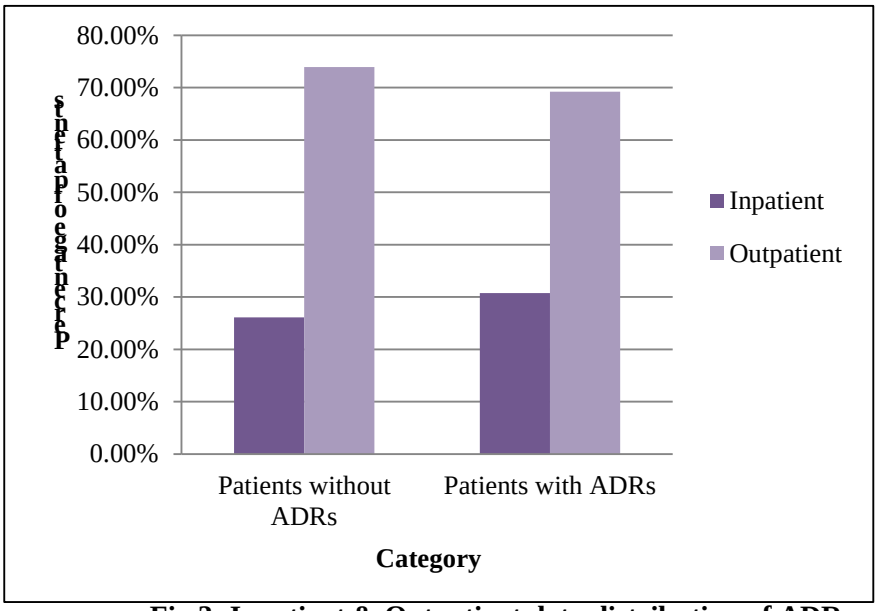

Fig.3: Inpatient & Outpatient data distribution of ADRs

4. System wise distribution of ADRs

Table.1: Pattern and prevalence of ADRs

Sl. No.	Adverse drug reactions	No. of occurrences	Percentage % (out of 39)
1.	**Neurological ADR**	17	43.58%
	Tremors	6	
	Insomnia	6	
	Sedation	2	
	Somnolence	2	
	Giddiness	1	
2.	**Gastro-intestinal** Constipation	2	5.13%
3.	**Metabolic** Weight gain	8	20.53%
4.	**Psychiatric/behavioral**	7	17.94%
	Mood Swings	1	
	Anxiety	2	
	Hallucination	2	
	Night Mares	1	
	Depression	1	

5.	**Sexual function** Impotency	 1	 2.56%
6.	**Others**	4	10.26%
	Slurred speech Increased salivation	1 3	
	Total	39	100%

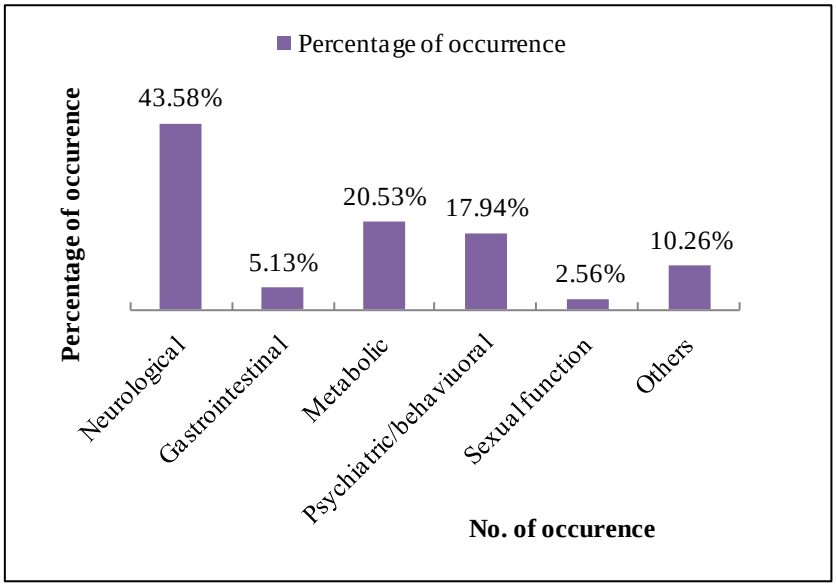

Fig.4: System wise distribution of ADRs

5. Disease Prevalence

Table.2: Disease prevalence

Disease	Total number of cases
Schizophrenia	63
Bipolar	29
Depression	29
Psychosis	17
Alcohol withdrawal	16
Anxiety	13
Behavioral	12
Epilepsy	15
Parkinsonism	03
Dementia	03
Total	200

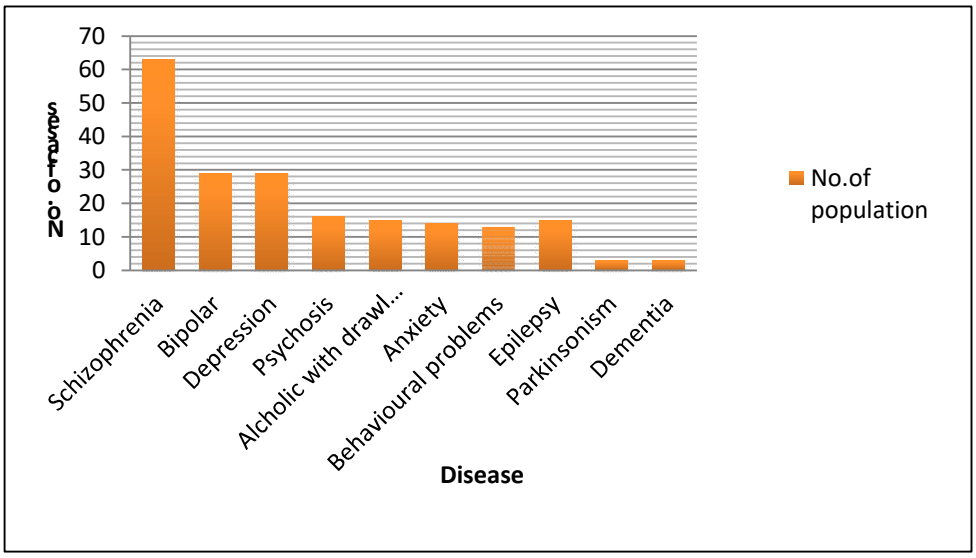

Fig.5: Disease prevalence rate

6. Types of ADRs with the drugs

Table.3: Types of ADRs and the drugs

Sl. No.	Type of ADR	Total number of ADRs	Drugs responsible for ADRs	Number of Occurrences
	Weight gain	8	Quetiapine Risperidone Olanzapine Risperidone+Clozapine Diazepam+Olanzapine Quetiapine+Olanzapine	1 2 2 1 1 1
	Insomnia	6	Fluoxetine Clozapine Alprazolam Sertraline Lithium	2 1 1 1 1
	Tremors	6	Sodium valproate Lithium Olanzapine Risperidone	2 1 1 1
	Anxiety	2	Fluvoxamine Sertraline	1 1
	Somnolence	2	THP Diazepam	1 1
	Constipation	2	Lorazepam	1

			Fluvoxamine	1
	Sedation	2	Haloperidol Clozapine	1 1
	Hallucination	2	Sodium Valproate THP	1 1
	Mood swings	1	Bupropion	1
	Depression	1	Clonazepam	1
	Impotency	1	Lithium	1
	Night mares	1	Propranolol	1
	Slurred speech	1	Olanzapine	1
	Giddiness	1	Alprazolam	1
	Increased salivation	3	Risperidone Clozapine	1 2

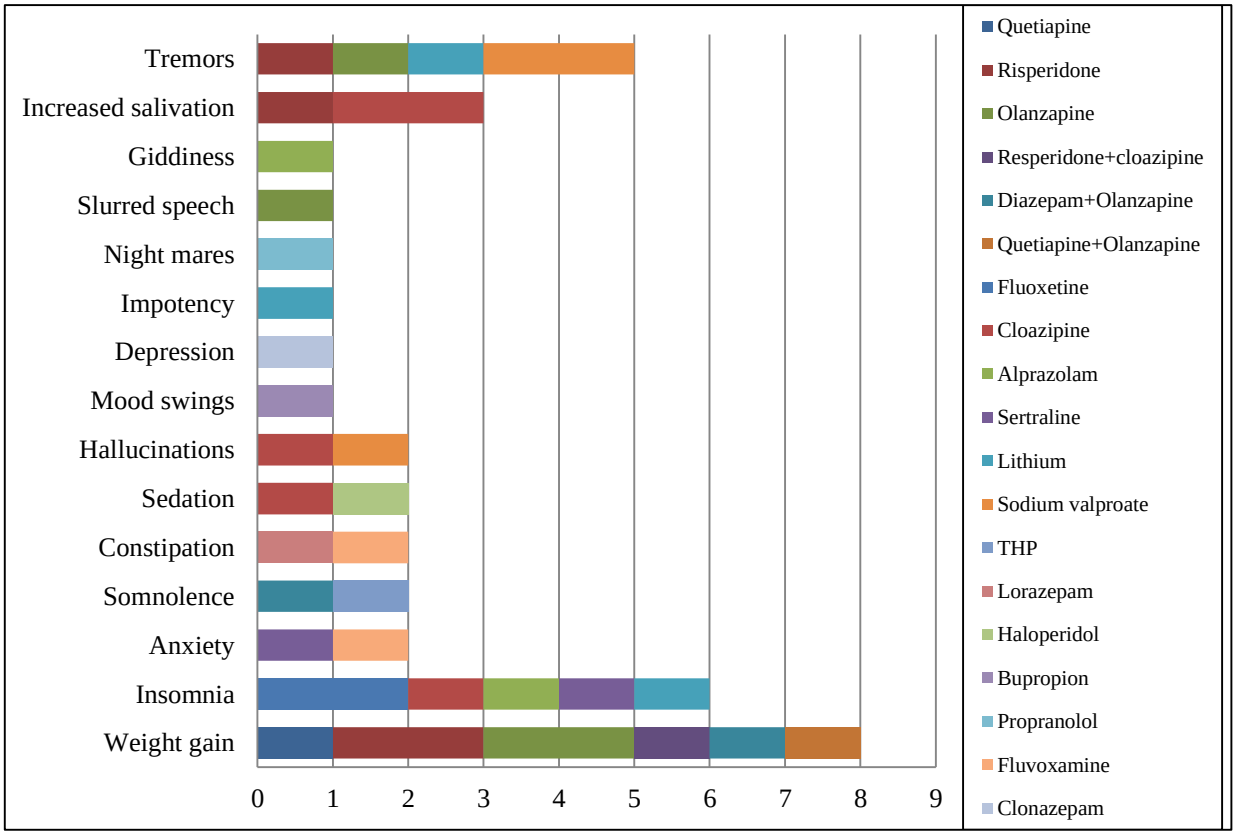

Fig.6: Types of ADRs and the drugs associated

7. Therapeutic class of drugs causing ADRs

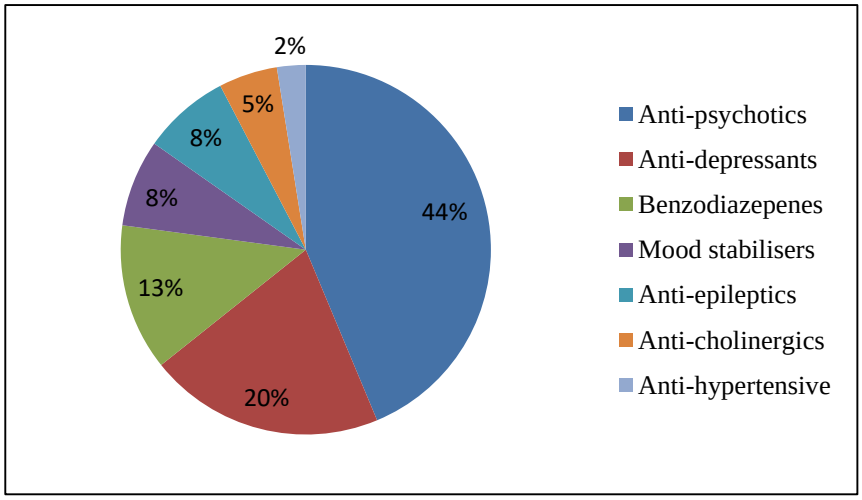

Fig.7: Therapeutic class of drugs causing ADRs

8. Causality Assessment

WHO Scale

Table.4: Causality Assessment

Assessment	Category	Number of ADRs
Causality (WHO scale)	Certain	0
	Probable	9(23.07%)
	Possible	26(66.66%)
	Unlikely	4(10.25%)

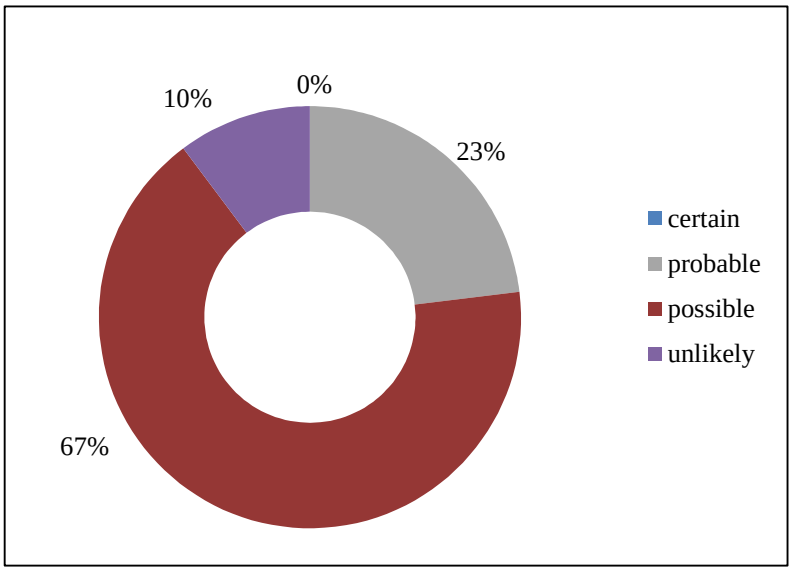

Fig.8: Causality Assessment

9. Severity (Hart wig And Siegel Severity Scale)

Table.5: Severity (Hart wig and Siegel Severity Scale)

Assessment	Category	No. of ADRs n (%)
Severity (Hart wig & Siegel severity scale)	Severe	0(0%)
	Moderate	12(30.76%)
	Mild	27(69.24%)

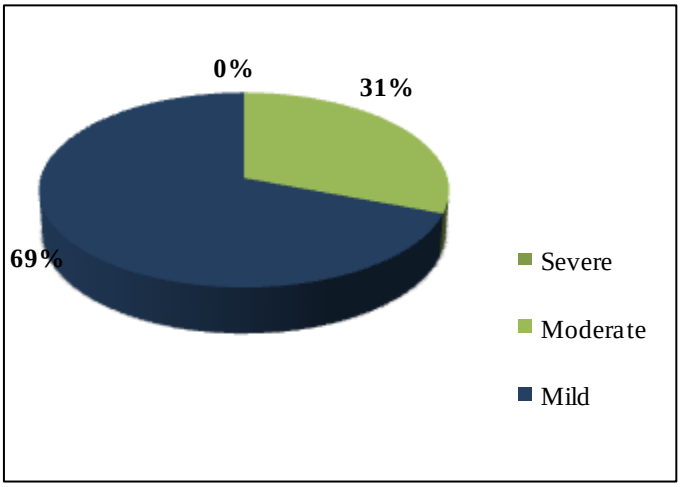

Fig.9: Severity (Hart wig and Siegel Severity Scale)

10. Preventability Scale (Shomuck & Thronton Preventability Scale)

Table.6: Preventability Scale (Shomuck & Thronton Preventability Scale)

Assessment	Category	No. of ADRs n (%)
Preventability scale (Shomuck & Thronton preventability scale)	Definitely preventable	23(58.97%)
	Probably preventable	9(23.07%)
	Not preventable	7(17.94%)

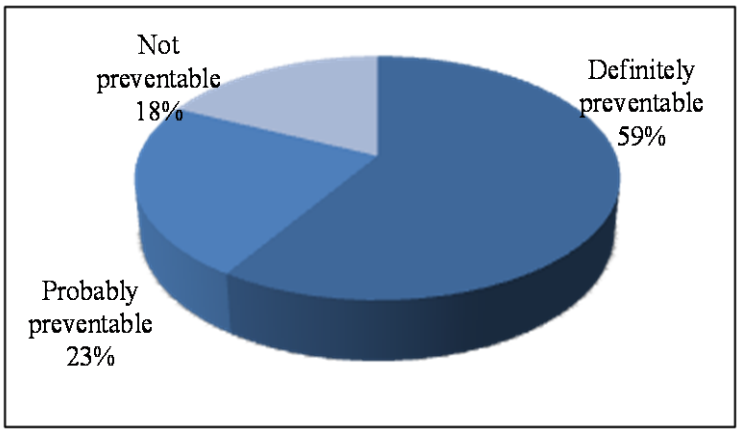

Fig.10: Preventability Scale (Shomuck & Thronton Preventability Scale)

11. Recommendations for preventing of ADRs

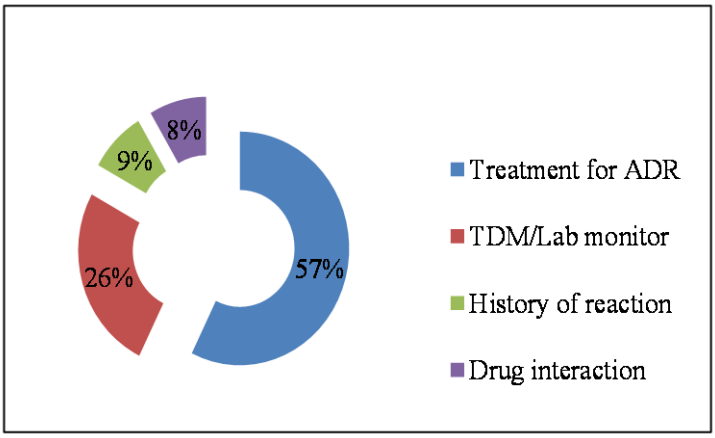

Fig.11: Preventability Scale (Shomuck & Thronton Preventability Scale)

12. Intervention by Clinical Pharmacist

Table.7: Intervention by Clinical Pharmacist

Sl. No.	REACTION	CLINICAL PHARMACIST APPROACH	MANAGEMENT OF ADRs
..	Constipation	Psychiatrist was informed that "Lorazepam" in patient therapy has evidence of Causing constipation	Treated with lactulose syrup
?.	Tremors	Evidences stated that anti-psychotics can cause tremors.	Dose of drug is reduced(if tremors are self-limiting) THP is given (if tremors are high)

3.	Somnolence	Evidences stated that “Diazepam” can cause somnolence.	Dose of drug was reduced/drug was indicated to take at night.
4.	Increased Sedation	Evidences stated that “Clozapine” can cause sedation	Dose of drug was reduced.
5.	Night mares	Evidences stated that “Propranolol” can cause night mares.	Drug withdrawn
6.	Leucopenia	Evidences stated that “Clozapine” can cause alterations in the total count.	Drug is closely monitored
7.	Increased weight	Evidences stated that “Risperidone” can cause metabolic side effects.	Patient is maintained on weight management program.
8.	Increased salivation	Evidences stated that antipsychotics can cause excess salivation.	No change

13. Acceptability of clinical pharmacist’s interventions

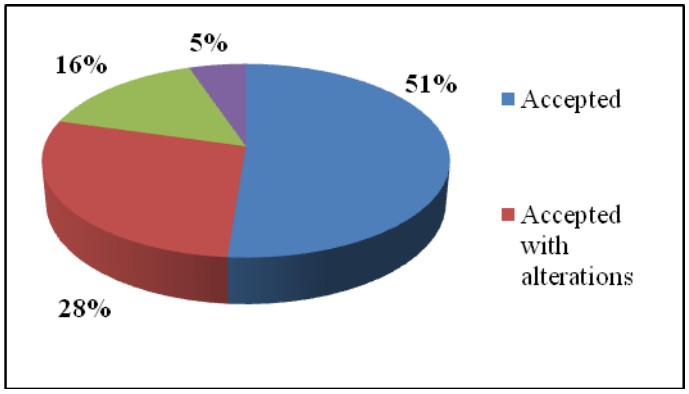

Fig.12: Acceptability of the clinical pharmacist interventions by Psychiatrist

14. Management of ADRs

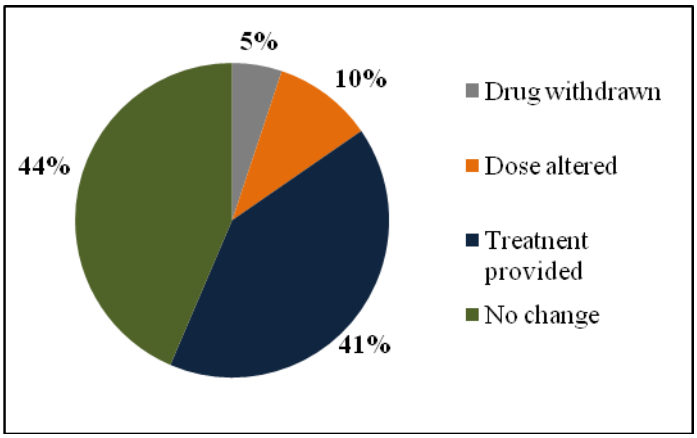

Fig.13: Management of ADRs

Management of ADRs was done may be by providing a specific treatment or by providing symptomatic treatment.

15. Outcome of ADRs

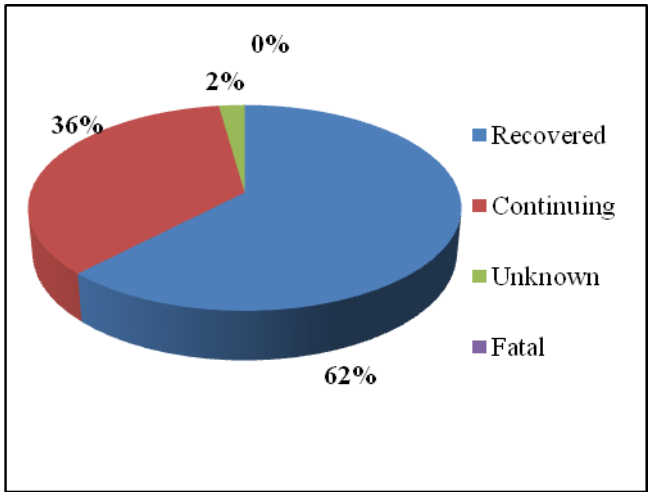

Fig.14 : Outcomes of ADRs

16. Adverse Drug Reaction Monitoring Centre (AMC) accepted ADR

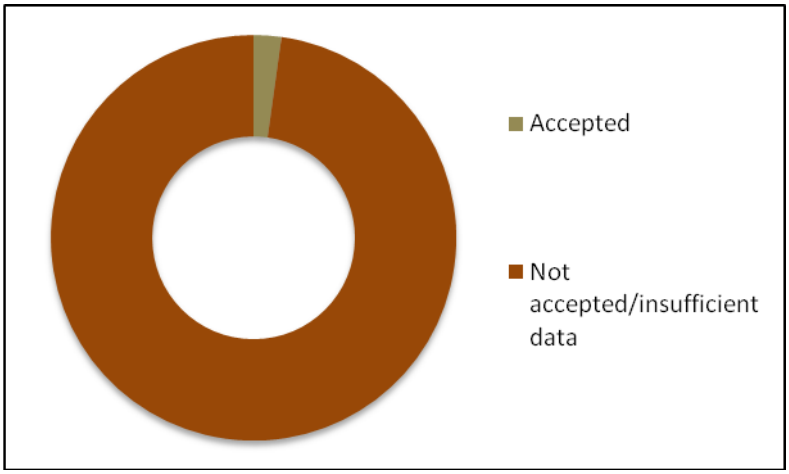

Fig.15: AMC accepted ADR with codes

DISCUSSION

The study creates a representative profile of probable ADRs in a tertiary care hospital's mental department. 200 patients participated in the trial, resulting in a total of 39 ADRs, of whom 26 were male and 13 were female.

According to the gender-specific data distribution (table.1), there are more males who have experienced adverse drug reactions (ADRs) than females, which is consistent with the male preponderance that was found in the study. Male predominance was also seen in the occurrence of disease cases and ADRs. The findings imply a correlation with earlier research where a male predominance was noted because of potential variations in pharmacokinetics, pharmacodynamics, pharmacogenetics, immunological, and hormonal variables. [2, 3]

The patients were divided into various age groups according to the data's age-wise distribution (table.2). According to this data, patients between the ages of 19 and 49 had

significantly high rates of illness and adverse drug reactions (ADRs). According to earlier studies, the psychiatrist may take the elderly and young patients into consideration and watch them more closely, give moderate doses, or avoid high risk medications and vulnerable combinations, which lowers the likelihood of adverse drug reactions in these populations.

The distribution of the inpatient and outpatient statistics (table.3) indicates that more outpatients than inpatients attend the hospital. Therefore, the occurrence of ADR was more frequently observed in outpatients than inpatients. This study's 19.5% incidence rate of ADRs was found to be comparable to that in other trials, where it ranged from 3.6% to 91%. [4, 5, 6]

A total of 39 ADRs were detected, and their system-by-system distribution shows that the majority of ADRs (43.58%) were found in the neurological system, followed by the metabolic and behavioural systems (20.53 and 17.94%, respectively). This may be because antipsychotic medications have a significant impact on metabolic and motor symptoms, which is consistent with the majority of research conducted. [7, 8]

Weight gain, sleeplessness, and tremors with the corresponding medicines were the three main categories of ADRs that were recorded. This shares similarities with other earlier investigations. According to the findings of earlier investigations, antipsychotic medicines (44%) were the most often implicated class of drugs in this study. [9]

According to other research conducted in the psychiatric department of a tertiary care hospital, patients with schizophrenia and other psychotic illnesses had the highest number of ADRs. [10] Due to their sedentary lifestyles and the involvement of other organ systems during the course of their condition, it appears that psychiatric patients are at a greater risk for having adverse drug reactions (ADRs) (long-term therapies required).

Analysis of the study's causality assessment revealed that there were no "certain" cases because the probable ADRs were primarily mild to moderate in severity. Due to the expected danger of the offending substance, re-challenge was not attempted; this is in agreement with the Brazilian study, in which 24 instances were determined to be "definite" after re-challenge was attempted.

Our study's findings about the incidence, seriousness, and preventability of ADRs can be used by the healthcare system to pinpoint which drugs ought to be the focus of patient education and quality improvement initiatives. Since the majority of the study's adverse drug reactions (ADRs) were predicted and hence preventable, it can be said that identifying targets in high-risk medications through thorough research will have a large impact on lowering avoidable ADRs.

Clinical pharmacists had made ADR interventions based on risk-benefit ratios and in the presence of doctors. Twenty of the 39 ADRs are approved, eleven are accepted with modifications, six are rejected, and two are not applied.

The outcome of the ADRs shows that there were no fatal ADRs reported, and that 62% of the ADRs were recovered and 32% of the ADRs were continuing. Management of ADRs was done by withdrawing the suspected drug in 10% of the cases, by changing the dose in 41% of the cases, by providing specific or symptomatic treatment in 44% of the cases, and by leaving it unchanged in 5% of the cases.

This study also offers details on clinical pharmacist intervention, which involves talking to patients about their medications, noting adverse drug reactions (ADRs), noting any implementations made by psychiatrists, and prescribing the right advice for the ADRs that

can be avoided. This helps to reduce the frequency of ADRs and maintain compliance. The quantity of interventions carried out supports the value of the pharmacist's participation in clinical activities.

AMC report numbers for 31 ADRs were given by the closest pharmacovigilance centre after the ADRs were reported via CDSCO's suspected ADR reporting form.

CONCLUSION

Clinical pharmacists may be more effective in preventing, detecting, and resolving ADR, which would ensure patient compliance. One significant achievement made throughout the research period in the institution was the inclusion of clinical pharmacists in routine clinical activities in inpatient and outpatient units, which was crucial to completing clinical pharmacists' tasks.

The goal of the current study was to monitor and report un favourable events that occur in a tertiary care hospital's mental unit. In conjunction with physician interventions, clinical pharmacists play a crucial part in the health management system. The submitted evidenced ADRs were handled for additional review after being reported. Even though necessary events were changed by different therapies, monitoring this class of medications still needs more research.

Additionally, the use of medications is a dynamic process, and clinical pharmacist interventions can result in improved results, improving pharmacotherapy's safety, effectiveness, and cost-effectiveness.

ACKNOWLEDGEMENT

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