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RESEARCH ARTICLE

A Retrospective Study of Adverse Drug Reactions and Their Treatment Patterns in Psychiatry Department of a Tertiary Care Hospital

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Abstract: Introduction: In today's scenario there are many cases of anxiety, depression, schizophrenia, manic depressive psychosis which are being treated in the Psychiatry department worldwide. There is a high prevalence of Adverse drug reactions due to anti-anxiety drugs, anti-psychotic drugs and anti-depressants in Psychiatry. Hence this study was planned. ***Objectives***: To study the pattern of adverse drug reactions caused by drugs used in Psychiatry, causality and severity of the reactions and treatment for the same. ***Methods***: All patients who reported an adverse drug reaction to drugs in the Psychiatry out patient department were included in the study. The data was recorded on a proforma. Pregnant and lactating women were excluded. The data was analyzed using descriptive statistics. ***Results***: There was a total of 103 ADRs recorded from 74 patients. CNS adverse drug reactions were the most common (45 cases,43.7%%) and in CNS, Sedation was the most common ADR (22 cases ,21.4%). Selective Serotonin re-uptake Inhibitors (SSRIs) caused the highest number of ADRs (23Cases,31%)). The drug was stopped in 12 patients (16%) while 27 patients (36.5%) required a dose reduction. Trihexyphenidyl was used to treat Extrapyramidal reactions. ***Conclusions***: Adverse drug reactions occur commonly in patients prescribed with drugs in Psychiatry and since dose reduction is one of the treatment modalities in our study it is advisable to start with a lower dose of the medication and if required gradually increase the dose to prevent ADRs in patients. Studies with larger sample size need to be carried out.

Keywords: Adverse drug reactions ,Drugs ,Psychiatry,Treatment

INTRODUCTION

There is an increasing number of mental illnesses in the world today .These illnesses require to be treated for a long duration of time with appropriate medications. These medications can cause adverse drug reactions and hence it is necessary to monitor these adverse drug reactions. An ADR, as per the WHO, is defined as "a response to a drug which is noxious unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or for modification of physiological function." These reactions pose a significant problem in view of increased morbidity and mortality, increasing costs of health care and poor compliance [1] .ADR monitoring in the hospital setting is vital because it helps to understand the nature and type of ADRs and to identify high-risk patients for developing ADRs [1]

Depression is a widespread mental disorder that can cause sadness, loss of interest, guilt, sleep and appetite disturbances, fatigue, and difficulty concentrating. It can impair one's ability to carry out the daily routine tasks and can lead to suicide. Mild cases can be treated without medication, but moderate to severe cases require medication and therapy [2].

Newer generation antidepressant drugs (ADs) are widely used as the first line of treatment for major depressive disorders and are considered to be safer than tricyclic agents. Selective serotonin reuptake inhibitors, serotonin noradrenaline reuptake inhibitors, bupropion, mirtazapine, trazodone, agomelatine, vilazodone, levomilnacipran and vortioxetine are the newer anti-depressants used in the therapy of Depression [3].

Among the pharmacological agents, a notable addition is the role of ketamine infusion in the rapid amelioration of depressive symptoms. Irrespective of the mode of administration, the studies are in agreement over ketamine's usefulness in helping reduce the symptoms of depression rapidly, from just the 40th minute onward[4]. However it has not been possible to maintain the efficacy of the Ketamine once the infusion is stopped .Not many studies are there which have monitored the adverse drug reactions to the newer anti-depressants .Among the anti-psychotics ,the atypical anti-psychotic drugs such as Risperidone, olanzepine, Quetiapine are usually preferred in the treatment of patients as they have better safety profile as compared to the conventional anti-psychotic drugs .However as seen in the study by Raakhi et al .[5] Risperidone and olanzepine caused weight gain

and sedation .The conventional anti-psychotics such as trifluperazine and Haloperidol caused tremors and dyskinesias .According to a study carried out by Vijetha et al Risperidone caused EPS in a significant number of patients [6] Clozapine, Olanzepine and Quetiapine cause dyslipidaemia as an important adverse effect [7].Anti anxiety medications are also known to cause a variety of adverse effects[8]. In order to provide good health care to patients there is a need to study and monitor the adverse effects of drugs . Patient safety is a concern for all physicians . Hence it was planned to study the pattern of the ADRs, their causality and severity and treatment of the ADRs caused by drugs used in the department of Psychiatry which includes anti-psychotic , anti-depressant and anti-anxiety medications .

The Causality assessment was carried out using the WHO -UMC (World Health Organsisation-Uppsala Monitoring Centre)scale . According to this the adverse drug reactions are classified as Certain, Probable, Possible, Unlikely, Unclassified and Unclassifiable [9] . The Severity assessment was carried out using the Hartwig -Seigel Severity Scale.The Adverse drug reactions were classified as Mild, Moderate or Severe [10] .

If an antipsychotic is providing substantial benefit, and the adverse effect is not life threatening , then the first management choice is to lower the dose or adjust the dosing schedule. Next is to change the antipsychotic; this is often reasonable unless the risk of relapse is high, such as when an individual has only responded to clozapine.
In some instances, behavioural interventions can be tried. Finally, concomitant medications, though generally not desirable are necessary in many instances[11]. The present study was carried out to find out if any other methods could be used to reduce the incidence and severity of the adverse drug reactions such as dietary advice, counselling for weight reduction ,increased fluid intake and changing the time of drug administration in addition to the other treatment modalities .

We also studied the adverse reactions to drugs used for other disorders of patients such as migraine who came for consultation to the Psychiatry OPD.

METHODS

This was a retrospective, observational study of adverse drug reactions and their treatment patterns in patients attending the Psychiatry department of a tertiary care hospital .The data of the patients who came to the Psychiatry OPD of a Tertiary care Hospital with an adverse drug reaction was collected from the Medical records department. The data of six months was collected from December 2024 to May 2025 after obtaining approval from the Ethics Committee of the Institution.

The Inclusion criteria and the Exclusion criteria for the study were as follows:

Inclusion criteria

- Age : 18-75years,
- Gender : Male and female
- All patients who attended the Psychiatry OPD with an adverse drug reaction

Exclusion criteria

- Pregnancy and Lactation

Study duration -The data from December 2024 to May 2025was collected .
The Institutional Ethical Committee approval was taken for the study. The retrospective data collection and analysis of the study was carried out. The demographic data of the patient, details about the diagnosis, the comorbid conditions if any, drug treatment data, adverse drug reaction data and the treatment administered for the adverse drug reaction were collected on a specially designed Proforma . The drug treatment data included the name of the drug, dose, route and frequency of administration of the drugs. In the adverse drug reaction data , the drug causing the reaction, the description of the reaction , the causality and severity was recorded. The causality of the reaction was assessed using WHO -UMC scale as Certain, Probable, Possible, Unlikely, Conditional/Unclassified or Unclassifiable [9].For certain, probable and possible categories a link with a drug was required. In case of polypharmacy the link was established on the basis of known adverse effects of that drug from literature.

The severity of the reaction was assessed using Hartwig Siegel Severity Assessment Scale as Mild, Moderate or Severe. Levels 1 and 2 are mild , Levels 3 and 4 are moderate, and Levels 5, 6 and 7 are classified as severe. In minor severity, there is no need of antidote, therapy or prolongation of hospitalization. Moderate severity requires a change in the drug therapy, specific treatment or an increase in hospitalization by at least 1 day. Severe class includes all potentially life threatening reactions causing permanent damage or requiring intensive medical care [12]. The treatment administered for the ADRs was also noted . This included withdrawal of the suspected drugs , dose reduction , change in time of administration of the drug ,dietary counselling for weight gain ,non-drug treatment modalities and drug treatments administered for the adverse drug reactions were recorded .

Statistical Analysis –The data has been analyzed using Descriptive Statistics.

RESULTS

A total of 103 ADRs were recorded from 74 patients in our study.

Age Distribution (Table 1)

The maximum number of patients were in the age group of 31-40 years(26 patients,35%) followed by 21-30 years(20 patients,27%)The least number of patients were in the age group of 61-70 years(3 patients,4%)

Gender distribution (Table 1)

Out of 74 patients ,41 were females (55%) and the remaining 33were males.(45%)

Diagnoses of the patients with ADRs (Table 2)

Depression was the most common diagnosis (15 patients,20.3%).There were 12 patients who presented with Headache (16.2%) and 8 patients who were diagnosed with Schizophrenia (10.8%)and 8 patients had Anxiety (10.8%).Obsessive Compulsive disorder was seen in 6 patients(8.1%).

Table 1. Demographic Characteristics of Study Population (n = 74 patients)

Variable	Category	n	%		
Age group (years)	11-20	6	8.1		
	21-30	20	27		
	31–40	26	35		
	41–50	14	18.9		
	51–60	5	7		
	61-70	3	4		
Gender	Male	33	45		
	Female	41	55		
Comorbid Conditions	None	73	98.6		
	Hypertension	1	1.4		
	Diabetes mellitus	-			

Table 2. Primary Psychiatric Diagnoses of Patients with ADRs (n = 74 patients)

DIAGNOSIS	NO. OF PATIENTS	PERCENTAGE OF PATIENTS
Depression	15	20.3
Headache	12	16.2
Anxiety	8	10.8
Schizophrenia	8	10.8
Obsessive Compulsive disorder	6	8.1
Alcohol Dependence Syndrome	4	5.4
Bipolar affective disorder	3	4.1
Dysthymia	2	2.7
Mental retardation	2	2.7
Acute Transient Psychosis	2	2.7
Others	12	16.2

Table 3. System Organ Class-wise ADR Distribution (n = 103 reactions)

System organ class	n	%
CNS	45	43.7
Gastrointestinal tract	21	20.4
Weight gain	9	8.7

Extrapyramidal effects	8	7.8
Endocrine	3	2.9
Appetite changes	5	4.9
Others (sweating,dry outh,Hairfall,lethargy Palpitations ,drooling,agitation)	12	11.7

Table 4. Drugs Implicated in ADRs by Class (n = 74 patients)

Drug Class	Drug Names	Patients with ADR	% of patients
SSRI	**Fluoxetine Paroxetine Escitalopram Sertraline**	**23**	**31.1**
TCAs	**Amitryptiline**	**10**	**13.3**
NASSAs	**Mirtazapine**	**9**	**12.1**
Anti-psychotics	**Risperidone Olanzepine Haloperidol**	**12**	**16.2**
Benzodiazepenes	**Lorazepam Clonazepam Chlordiazepoxide**	**9**	**12.1**
Others (SNRI,Atypical anti-depressant,anti-epileptics,muscle relaxant,NSAIDs)	**Venlafaxine Duloxetine Oxcarbazepine Baclofen Ibuprofen**	**11**	**14.9**

Table 5:Causality Assessment of ADRs (WHO-UMC Scale, n = 103 reactions)

Causality	Total n (%)	SSRIs n (%)	TCAs n (%)	Other anti-depressants n (%)	Anti-psychotics n (%)	BZDs n (%)	Others n (%)
Certain	25 (24.2)	8 (32)	7 (28)	3 (12)	5 (20)	1 (4)	1 (4)
Probable	66 (64)	24 (36.4)	6 (9.1)	3 (4.54)	12 (18.2)	5 (7.6)	10 (15.2)
Possible	12 (11.6)	6 (50)	-	-	-	2 (16.7)	4 (33.33)

Table 6. Severity Assessment by Drug Class (n=103 reactions)

Severity	Total n (%)	SSRIs n (%)	TCAs n (%)	Other anti-depressants n (%)	Anti-psychotics n (%)	BZDs n (%)	Others n (%)
Mild	47 (45.6)	20 (45.5)	3 (6.3)	4 (8.5)	4 (8.5)	4 (8.5)	12 (25.5)
Moderate	56 (54.4)	18 (32.1)	10 (17.9)	9 (16.1)	13 (23.2)	4 (7.1)	2 (3.6)

Table 7 Severity in Polypharmacy vs. Monotherapy

Severity	Monotherapy ADRs (%)	≥ 2-Drug ADRs (%)
Mild	… 24 (37.5)	…23 (59)
Moderate	… 40 (62.5)	…16 (41)

Table 8. Management Strategies for patients with ADRs (Total=74 patients)

Strategy	**n**	**%**	
Withdrawal of suspected drug	12	11.65	
Dose reduction	27	26.21	
Change in administration timing	7	6.7	
Symptomatic pharmacotherapy	9	8.73	
Non-drug interventions	27	26.21	

Strategy	**n**	**%**
Dietary counselling	6	5.82

Pattern of Adverse Drug Reactions (Table 3)

Central nervous system adverse drug reactions were the most common(38 cases,37%)

In ADRs of the CNS, sedation was the most common ADR seen in 22 patients (21.4%)In the CNS the other ADRs seen were headache, dizziness, lack of concentration, mental confusion, and restelessness.(16 cases,15.5%). Insomnia was seen in 7 patients (6.7%) Hence the total number of CNS ADRs was 45 .This was followed by gastrointestinal ADRs (21 cases,20%)which included constipation ,nausea, gastritis, vomiting and abdominal pain.. Weight gain occurred in 9 patients(9%) Extrapyramidal symptoms and Tremors were recorded in 8 patients(7.7%).Increased appetite ,sexual dysfunction, sweating and dryness of mouth were seen as ADRs in 3 patients each (2.9% each).There was reduction in appetite in 2 patients and the other Adverse reactions seen were hairfall, facial flushing, drooling, lethargy, palpitations and agitation(6 cases,5.8%).

Drugs implicated in ADRs by class (Table 4)

The Selective Serotonin reuptake Inhibitors were responsible for ADRs in 23 patients(31%).In these SSRIs the number of ADRs were Fluoxetine (6 cases),Paroxetine (6 cases),Escitalopram(6 cases) and Sertraline (5 cases).In 11 patients ADRs were caused by Atypical anti-psychotic drugs(15%).The single drug which caused ADRs in maximum number of ADRs was Amitriptyline (10cases,13%).

The individual drug classes and drugs which caused the adverse drug reactions are shown in **Table 4**.Amitryptiline caused ADRs in 10 patients, followed by Mirtazapine (9 patients) .However the SSRIs which includes Fluoxetine,(6 cases) Paroxetine (6 cases),Escitalopram(6 cases) and Sertraline (5 cases) totalled to a number of 23 cases. Olanzepine also caused ADRs in 6 patients

Causality Assessment of the Adverse drug Reactions (Table 5)

The Causality was assessed according to the WHO-UMC Causality Assessment Scale.

The maximum number of adverse drug reactions were Probable (66 reactions, 64 %),followed by Certain (25 reactions, 24.2%) and then Possible (12, 11.6%).SSRIs were responsible for the highest number of Certain reactions as also the Probable reactions

Severity of ADRs (Table 6)

- The severity of the adverse drug reactions was assessed according to the Hartwig Siegel Severity Scale as Mild, Moderate or Severe.
- The majority of the reactions were Moderate (56 reactions,54.4%) and 47 reactions were of mild severity (45.6%).No severe reactions were encountered during the period of our study.

The SSRIs were responsible for the highest number of moderate 18 out of 56 (32.1%)as well as mild 20 out of 47(45.5%) reactions.

Polypharmacy and Severity of ADRs (Table 7)

Out of the study population of 74 patients ,the number of patients who were administered only one drug was 51.Twenty three patients received more than one drug. There were 40 reactions of moderate severity in the 51 patients and 16 reactions of moderate severity in the 23 patients .Refer **Table 7.**

There was only one patient who developed four ADRs and that patient had received two drugs namely Clonazepam and Sertraline .

Management of the ADRs

The dose of the offending drug was reduced in 27 patients, the drug was changed to morning administration in 4 patients and night administration in 3 patients. In 12 patients the drug was withdrawn due to ADR. The ADRs due to which the drugs were stopped were sedation, dizziness, vomiting ,sexual dysfunction ,decreased appetite and gastric discomfort and dryness of mouth.

Treatment of Adverse drug Reactions (Table 8)

The treatment modalities for the various adverse drug reactions are shown in Table 8

For sedation the dose of the drug was reduced in 15 patients and in 3 patients the administration was changed to night. Trihexyphenidyl and Propranolol were the drugs sued for the treatment of extrapyramidal reactions , tremors and ataxia. For weight gain only counselling about exercise and diet control was told . Insomnia was treated by dose reduction in 2 cases and morning administration in 4 cases. Dizziness was treated by asking the patient to increase fluid intake, take medication after food dose reduction. Nausea, constipation ,and headache were treated with methods like hydration, after food administration and dose reduction where drugs were not given .

DISCUSSION

In our study, adverse drug reactions of moderate severity were predominant with SSRIs accounting for the maximum number of "Certain" reactions. Many studies have been conducted in the past to study adverse drug reactions to psychotropic drugs but not many studies have addressed the management strategies . Hence we wanted to also study the management of these ADRs in the outpatient department of Psychiatry in our Hospital. Consistent with the studies done by D'Souza et al [12] Dharman et al [13] and Sidhu et al [14]the age group of 31-40 years accounted for the largest share of ADRs (35%)in our study also. This suggests that this demographic may be inherently more susceptible to psychotropic side effects because patients in this age group are more worried about their health and use far more health care facilities .

The number of ADRs in females was higher(55%) than that in males (45%) which is similar to studies by Angadi et al[15] ,Sharma et al [16] and Arya Jayashree et al[17] but different from the study by D'Souza et al where the numbers were equal in both the genders. In our study Depression was the most commonly diagnosed psychiatric illness and Depression is more common in females than males .Hence the adverse drug reactions were higher in the females .The number of males was higher in the study by Chawla et al [18].The Causality of the reactions was of Probable category in 52 % of cases ,Certain in 22 % and Possible in 1%.In the study by Dharman et al[13] the Causality was highest in the probable category which is similar to our study. Severity of the reactions was classified by the Hartwig's Scale and we found that majority of the ADRs were moderate (77%) and the rest were mild ADRs(23%). which is different from the study by Nalini et al .[19]Bag et al study also showed more ADRs in the mild category as compared to moderate category[20] but similar to the study by Dharman et al. Most patients had one Adverse drug reaction (70%), followed by 22 % cases who had 2 ADRs.7% cases had 3 ADRs and 1 case had four ADRs. This is similar to the study by D'Souza et al .This is because monotherapy was administered in most patients (54patients,73%)

The ADRs related to the central nervous system were the most in number (37%) which was similar to the study by Bag e t al [20]and Ejeta et al [21] and among them, sedation was the most common ADR (22 cases,21%)Many studies have reported weight gain as the most common side effect. This difference in reporting is due to the difference in prescribing pattern of medications and also due to the difference in diagnosis .Amitriptyline and Benzodiazepenes were the 2 of the causative drugs for the sedation Most of the psychotropic drugs cause somnolence by either enhancing the effect of gamma-Aminobutyric acid (GABA) at GABA-A receptor(e.g. benzodiazepines) or by increasing the level of serotonin in the synaptic cleft (e.g. antidepressants).
The gastrointestinal ADRs included constipation, vomiting, and gastritis. In the study by Shaikh F et al [22], CNS ADRs were the highest followed by gastrointestinal ADRs which is similar to our study. Weight gain occurred in 9 cases (9%). These results are similar to the Bag et al study. A variety of complex mechanisms accounts for the weight gain associated with antipsychotics, which includes the interaction between various neurotransmitters like serotonin and dopamine, genetic mechanisms, and activation and interaction between orexigenic and anorexigenic peptides.

Affecting about 1 in 5 patients [23], EPS are one of the most significant ADRs of treatment with APDs .(Anti-psychotic drugs) In the study by Abu Naser et al the cumulative incidence of drug-induced extrapyramidal symptoms (di-EPS) ranged from 9.8% [Amitriptyline 25mg] to 28.9% [Imipramine 25mg] [24].In our study, extrapyramidal reactions and tremors occurred in 8 cases (7.7%)In the study by Rani Kumari et al [25]dizziness seen with SSRIs was the most common ADR.

As regards the drugs causing the ADRs the number of ADRs caused by Selective Serotonin Reuptake Inhibitors was the highest (23 patients ,31%).Our study matches with other studies such as Rani Kumari et al [25],and Sidhu et al[13].This is because of the commonly diagnosed condition which was depression in these studies .But in the study by Mahakalkar et al[26] it was Atypical anti-psychotics while in the study by Dharman et al [12] it was specifically the anti-psychotic drug Risperidone. In another study done by Singh et al it was both Risperidone and SSRI (Escitalopram) [27].These differences are due to the differences in diagnosis and prescribing practices due to which the class of drugs used is different .

Sedation was caused by Amitriptyline and Benzodiazepenes (7 cases each) ,SSRIs (3 cases)while other CNS ADRs such as Insomnia caused by SSRIs (7 cases) dizziness by Bupropion, Mirtazapine and Oxcarbazepine was recorded. Since the drugs act on the CNS, hence it is expected that CNS adverse drug reactions will be the maximum.In the study by Kumari et al dizziness was the most common ADR. In the study by Sneha et al sedation was the most common ADR[28].
The most common diagnosis in our study who presented with ADRs was Depression (20%). This is similar to the studies conducted by Sidhu et al[13] , Jayashree et al [16], Kumari et al [27] and Johanna Seifert et al[29] .However in the study by D'Souza et al [11]and Dharman et al[12] it was Bipolar Affective Disorder .

Management of ADRs

Medication stopped

There was a need to stop the medication in 12 patients (16.2%)as the ADR was moderate in severity. The drugs which were discontinued due to ADR were SSRIs, Mirtazapine, Amitryptiline ,Baclofen, Clonazepam and Escitalopram. The drug causing the ADR was withdrawn or the dose altered in other studies such as Sridhar et al[30] and Ejeta et al [21] .

Dose modification

Dose reduction was done in 27 patients out of 74(36.4%).The drugs which were shifted to morning administration was changed due to Insomnia as an ADR (4 cases,5.4%) and for the treatment of sedation the dose was shifted to night (3 cases,4%)

Drug Therapy for ADR

Regarding drug treatment of ADR, Trihexyphenidyl and Propranolol were used for the treatment of EPS and tremors . Even in studies carried out by Stroup and Gray [11] Benztropine has been used for dystonias and Propranolol for akathisia. For the treatment of insomnia , Clonazepam was administered. It is well known that Benzodiazepene group of drugs are the treatment of choice in Insomnia.

Non-drug Therapy

Diet control and exercise was advised for weight gain. This is similar to the strategy employed in the studies done by Madhubashinee [31] and Stroup [11]. Sedation was treated with dose reduction (15 cases) and shift to night dose (3 cases) and Insomnia was treated by shifting the drug to morning administration (4 cases) and dose reduction(2cases). Dizziness was treated with hydration (2cases) and after food (2 cases) drug administration. Patients who had nausea were advised to take medication after food (4 cases) and the dose was reduced in one patient. Patients who had constipation were advised to take more fluids (22 cases)and dietary fibre (3 cases),while those who got headache were told to take the medication after food (2 cases) and increase fluid intake also (1 case) The dose reduced in 3 patients due to headache
.
In one study they have suggested Therapeutic drug monitoring to be done for inpatients in Psychiatry to prevent the occurrence of ADRs in these patients [32].

Limitations of our study was that it was conducted in one centre and it was a retrospective study. There is likelihood of under reporting of adverse drug reactions.

The duration of the study was also short.
In future prospective studies of longer duration of polypharmacy associated ADRs in geriatric patients can be carried out. Studies involving the in-patients and OPD patients in Psychiatry also can be done .

CONCLUSION

Given that dose reduction emerged as the most common management strategy for ADRs, clinicians should consider initiating psychotropic therapy at lower doses and titrating based on tolerability. The other important treatment modality was dietary counselling to treat weight gain and increased fluid intake to counter dizziness . Adverse drug reactions were frequent, with moderate-severity and probable causality predominating. Dose reduction proved an effective management strategy; accordingly, starting at lower doses and gradual escalation may minimise ADR risk. The limitation of the present study was that it was a retrospective study conducted for a short duration of time in a single centre. Future studies need to be carried out with larger sample size and targeted drug populations such as the geriatric age group to examine the incidence of ADRs and also evaluate polypharmacy risks. A multidisciplinary approach which involves the clinician and the pharmacologist, is required to prevent, diagnose and treat adverse drug reactions .

Conflicts of interest: None

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