Research Article

Evaluation of Suspected Adverse Drug Reactions of Psychotropic Drugs in a Tertiary Care Hospital of East India

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ABSTRACT

Mentally ill patients need lifelong treatment with psychotropic drugs that predetermine the ADR network. The common adverse effects associated with psychotropic drugs are weight gain, somnolence, tremors, and tardive dyskinesia. These adverse effects tend to deteriorate the mental and physical well-being of the patient and thus lead to patient's non-adherence to therapy. Setting standards and assessing the safety of care through performance review should become part of everyday clinical practice. Keeping this in mind, present study was conducted to highlight pattern of Adverse Drug Reactions with use of oral anti-diabetic drugs. All suspected Adverse Drug Reaction Reporting Form having any psychotropic drug as suspected cause of ADR was analyzed. Patient on psychotropic drug were screened for suspected ADRs and were reported to AMC (Adverse drug reaction Monitoring Centre), Department of Pharmacology. The reported ADRs on the notification forms, after being confirmed by the physician-in-charge, were assessed for causality using WHO-UMC Causality Categories, and preventability using Modified-Schumock and Thornton scale. Descriptive analysis was done for comparative analysis of data using numbered analysis. Majority of ADRs were found in female (56.6%). Majority of ADRs were observed in 31-40 years of age group (40.41%). Most commonly reported ADR was weight gain (17.11%) followed by sedation (12.39%), Diarrhoea (12.39%) and insomnia (11.80%). Most cases of weight gain were reported by patients receiving atypical antipsychotics (42 out of 58). Causality assessment according to WHO-UMC criteria showed 59% ADRs had probable causality while 40.12% had possible causality and only 0.88% had certain causality. The study results strongly suggest the need for healthcare professionals to focus more on assessment and reporting of suspected ADRs for generating more evidences for clinician to plan accordingly to reduce the cases of preventable ADRs. There is a need for evidence-based psychiatry which integrates with day-to-day clinical care. There is a need to integrate newer trends which are evidence based and have the potential to improve outcome and overall treatment results.

Keywords: Adverse Drug Reaction, Psychotropic Drugs, Mental illness, Pharmacovigilance.

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INTRODUCTION

Mental disorders are often associated with significant stress in family life, social life, workplace, or other important activities. [1] Major proportions of mental disorders come from low and middle income countries. [2] Psychiatric disorders form an important public health priority and major causes of morbidity. [3] Of the top ten health conditions contributing to the Disability Adjusted Life Years (DALYs), four are psychiatric disorders. [4]

For the treatment of psychiatric disorders, a wide array of psychotropic drugs is available. [5] Psychiatrists are now very keen to use newer psychotropic medications in psychiatric practice which require vast study on their utilization and consequences on real life effectiveness and safety in actual clinical practice. [6]

An adverse drug reaction (ADR) is defined by the World Health Organization (WHO) as "any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function". [7] ADRs are the most common drug related adverse event that occur across the world. [8]

The discovery of Adverse Drug Reactions (ADRs) has become significant due to the introduction of large amounts of drugs over the past two decades. Adverse drug reactions that occur daily in hospitals are detrimental to the patient's health but are often not reported that lead to serious illness and death. Care should be taken to identify development of suspected sign and symptoms in patients who are taking too many drugs and have much co-morbidity. The drugs that often cause ADR should be put in category of high suspicion. The increase in drug supply

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in the market, the increase in unscientific promotional activity by pharmaceutical representatives and increased trend of poly-pharmacy due to individual drug for individual symptom are factors that contribute to the growing evidence and complexity of ADRs around the world. Adverse drug reactions can lead to a patient's loss of confidence in treatment that leads to negative feelings about his or her doctor and discontinuation of treatment and involvement with treatment options, which in turn can reduce further ADRs and increase mortality and morbidity in people. [9]

Mentally ill patients need lifelong treatment with psychotropic drugs that predetermine the ADR network. [10] The common adverse effects associated with psychotropic drugs are weight gain, somnolence, tremors, and tardive dyskinesia. These adverse effects tend to deteriorate the mental and physical well-being of the patient and thus lead to patient's non-adherence to therapy. [11]

Studies show that the psychotropic drugs most commonly associated with ADRs are antipsychotics and mood stabilisers. Among antipsychotics, conventional antipsychotics (haloperidol) have a higher incidence of ADRs compared to atypical or second generation antipsychotics (olanzapine and risperidone). [12] On the other hand, cardio-metabolic side effects with atypical antipsychotics pertain to be a matter of conflict even though they have a lower risk for developing extrapyramidal side effects (EPS). [13] The epidemiological statistics of ADR is justified by its high prevalence rate, which varies from three to six per cent of hospital admissions in adults and 24% in the elderly population. They rank fifth among the causes for mortality and attributes for five to ten per cent of hospital costs. [14]

Setting standards and assessing the safety of care through performance review should become part of everyday clinical practice. Keeping this in mind, present study was conducted to highlight pattern of Adverse Drug Reactions with use of oral anti-diabetic drugs.

MATERIALS AND METHODS

This was an observational and open label study carried out in AMC (Adverse Drug Reaction Monitoring Centre) in department of pharmacology of a tertiary care hospital of east India. Permission from Institutional ethics committee was taken for collection, analysis and publication of data before starting this study. Informed consent was also obtained from the patients whose data were analyzed.

The duration of study was 18 months. All suspected Adverse Drug Reaction Reporting Form having any psychotropic drug as suspected cause of ADR was analyzed. Patient on psychotropic drug were screened for suspected ADRs and were reported to AMC (Adverse drug reaction Monitoring Centre), Department of Pharmacology. The screening was carried out by senior residents of psychiatry department for interviewing psychiatric patients.

Inclusion Criteria

Patients between 12 to 60 years of age and of all gender, Patient visiting the psychiatry OPD, Receiving psychotropic drugs, Diagnosis of psychiatric illness as per ICD 10 Criteria107

Exclusion Criteria

Patients below 12 years of age and above 60 years of age, Prescriptions without any psychotropic drugs, Patients with diagnosis of Mental retardation, Patients with diagnosis of Dementia, Patients on stimulant drugs

The adverse drug reaction resulting from overdosing and drug interactions were excluded. The forms having doubtful history and missing data was also excluded from the study.

The reported ADRs on the notification forms, after being confirmed by the physician-in-charge, were assessed for causality using WHO-UMC Causality Categories, [15] and preventability using Modified-Schumock and Thornton scale [16].

Statistical Analysis

Results obtained from this study were presented in tabular form and data was interpreted by using Microsoft Excel 365 software. Descriptive analysis was done for comparative analysis of data using numbered analysis.

RESULTS

After applying inclusion and exclusion criteria, 500 suspected ADR reporting forms were found suitable for analysis.

Table 1: The Different Types of Adverse Drug Reactions (ADRs) that occurred during the study period

Type of ADR	Number of ADR	Percentage of ADR
Weight Gain	58	17.11
Sedation	42	12.39
Dizziness	30	8.85
Insomnia	40	11.80
Headache	28	8.26
Akathisia	18	5.31
Tremor	20	5.90
Dry Mouth	16	4.72
Fatigability	16	4.72
Anorexia	14	4.13
Sexual Dysfunction	5	1.47
Nausea	14	4.13
Abdominal Pain	14	4.13
Constipation	12	3.54
Rash	7	2.06
Palpitation	5	1.48
TOTAL	**339**	**100**

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Weight gain (17.11%) was most frequent ADR followed by sedation (12.39%) and insomnia (11.80%). 11.8% of total ADR were GI side effects.

Table 2: Distribution of Suspected ADRs According to Responsible Antipsychotic and Anti-manic Drugs

Drugs / ADRs	Flupentixo	Haloperido	Levosulpiride	Olanzapine	Quetiapine	Lurasidone	Amisulpride	Risperidone	Trifluoperazine	Divalproex Sodium	Oxcarbazepine
Weight Gain	-	-	-	10	19	3	3	7	-	-	-
Sedation	-	-	-	7	7	4	3	-	-	4	-
Dizziness	-	-	-	-	-	-	-	-	-	-	-
Insomnia	-	-	-	4	-	-	5	-	-	-	-
Headache	-	-	-	4	3	-	-	-	-		5
Akathisia	5	3	2	-	-	-	-	-	6		-
Tremor	6	3	2	-	-	-	-	-	7		-
Dry Mouth	-	-	-	3	4	2	3	-	-	4	-
Fatigability	-	-	-	-	-	-	-	-	-		-
Anorexia	-	-	-	-	-	1	-	4	-		-
Sexual Dysfunction	-	-	-	-	1	-	-	-	-		-
Nausea	-	-	-	-	-	-	-	-	-		3
Abdominal Pain	-	-	-	2	1	-	-	-	2		-
Constipation	-	-	-	-	-	1	1	2	-	2	-
Rash	-	-	-	-	1	1	-	1	-		2
Palpitation	-	1	-	-	1	1	-	2	-		-

Weight gain was mostly associated with atypical antipsychotics whereas extra-pyramidal side effects were major concern with typical antipsychotics.

Table 3: Distribution of Suspected ADRs According to Responsible Antidepressants and Anti-anxiety Drugs

Drugs / ADRs	Fluvoxamine	Paroxetine	Sertraline	Fluoxetine	Nortriptyline	Venlafaxine	Escitalopram	Lorazepam	Clonazepam
Weight Gain	-	3	-	-	6	-	7	-	-
Sedation	-	1	4	4	-	-	-	4	4
Dizziness	3	3	6	6	-	-	-	6	6
Insomnia	-	-	8	7	-	6	10	-	-
Headache	2	3	2	2	-	7	-	--	-
Akathisia	-	-	-	-	-	-	2	-	-
Tremor	-	-	-	-	-	2	-	-	-
Dry Mouth	-	-	-	-	-	-	-	-	-
Fatigability	-	-	-	-	7	-	4	2	3
Anorexia	1	2	4	2	-	-	-	-	-
Sexual Dysfunction	-	1	1	-	-	2	-	-	-
Nausea	1	-	3	2	-	1	4	-	-
Abdominal Pain	-	-	1	1	2	1	4	-	-
Constipation	-	-	-	-	3	3	-	-	-
Rash	-	-	-	-	2	-	-	-	-
Palpitation	-	-	-	-	-	-	-	-	-

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Sedation and dizziness were mostly associated with use of SSRIs and benzodiazepines. Gastrointestinal adverse effects were most commonly associated with SSRIs and SNRIs.

Table 4: Distribution of Suspected ADRs according to WHO-UMC Causality Categories

Type of ADR	Number of ADR	Certain (%)	Probable/Likely (%)	Possible (%)
Weight Gain	58	1 (1.72%)	35 (60.34%)	22 (37.93%)
Sedation	42	0	25 (59.52%)	17 (40.48%)
Dizziness	30	0	16 (53.33%)	14 (46.67%)
Insomnia	40	1 (2.5%)	22 (55%)	17 (42.5%)
Headache	28	1 (3.57%)	16 (57.14%)	11 (39.28%)
Akathisia	18	0	12 (66.67%)	6 (33.33%)
Tremor	20	0	13 (65%)	7 (35%)
Dry Mouth	16	0	9 (56.25%)	7 (43.75%)
Fatigability	16	0	10 (62.5%)	6 (37.5%)
Anorexia	14	0	8 (57.14%)	6 (42.86%)
Sexual Dysfunction	5	0	3 (60%)	2 (40%)
Nausea	14	0	9 (64.28%)	5 (35.71%)
Abdominal Pain	14	0	8 (57.14%)	6 (42.86%)
Constipation	12	0	7 (58.33%)	5 (41.67%)
Rash	7	0	4 (57.14%)	3 (42.86%)
Palpitation	5	0	3 (60%)	2 (40%)
TOTAL	339	3 (0.88)	200 (59%)	136 (40.12)

Most of the ADRs were probably related to the culprit psychotropic drugs. Only 1 ADR each of headache (fluvoxamine), insomnia (sertraline) and weight gain (olanzapine) were certainly related to culprit psychotropic drugs.

Table 5: The Age Group and gender wise distribution of patients with Adverse Drug Reactions (ADRs)

Age Group	No of ADRs	Percentage of ADRs (Out of 339 ADRs)
12-20	25	7.37
21-30	87	25.67
31-40	137	40.41
41-50	52	15.34
51-60	38	11.21
Gender		
Female	192	56.6
Male	147	43.4

Most number of ADRs was found in patients of reproductive age group (21-30 & 31-40). Female patients reported ADR more frequent than males.

Table 6: Distribution of ADRs based on Preventability using Modified-Schumock and Thornton scale

Age Group	No of ADRs	Percentage of ADRs (Out of 339 ADRs)
Definitely Preventable ADRs	104	31%
Probably preventable ADRs	39	11%
Non Preventable ADRs	196	58%

DISCUSSION

In our study, a total of 339 ADRs were found in 500 patients. Majority of ADRs were found in female (56.6%). Majority of ADRs were observed in 31-40 years of age group (40.41%) followed by 25.67% ADRs in 21-30 years of age group, 15.34% ADRs in 41-50 years of age group, 11.21% ADRs in 51-60 years of age group and 7.37% ADRs in 12-20 years of age group.

Most commonly reported ADR was weight gain (17.11%) followed by sedation (12.39%), Diarrhoea (12.39%) and insomnia (11.80%). 14 cases (4.13%) of akathisia tremor was found in our study. 18.29% of ADRs were Gastrointestinal side effects. Weight gain is more obvious with long term therapy especially with antipsychotics. A

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variety of complex mechanisms accounts for the weight gain associated with antipsychotics, which includes the interaction between various neurotransmitters like serotonin, dopamine, genetic mechanisms, and activation and interaction between orexigenic and anorexigenic peptides. Most of the psychotropic drugs cause somnolence by either enhancing the effect of gamma-Aminobutyric acid (GABA) at GABAA receptor (e.g.benzodiazepines) or by increasing the level of serotonin in the synaptic cleft. (e.g.antidepressants).

In a study conducted by Singh et al. total of 106 patients were suspected of having at least one ADR out of the 202 participants. Of 106 patients 47(44.33%) were males and 59(55.66%) were females. They found majority of ADRs in 25-35 years of age group (40.56%) with most commonly reported ADR of weight gain (18.86%) followed by sedation (16.03%) and insomnia (11.32%). [17]

In our study females were found to be more affected by ADRs. Similarly, a higher incidence of 54.85% ADRs was identified among female psychiatric patients in a study conducted on identification and management of antipsychotics ADR by Lucca et al. [18] These findings are supported by a study conducted by Lahon et al. [19] Apart from the common ADRs, EPS like akathisia and tardive dyskinesia were observed more in females which might be related to the hormonal influence in females (higher levels of oestrogen).

Even though majority of ADRs were observed in 31-40 years of age group, our study findings showed that nearly all the elderly patients (>51years) included in our study experienced at least one ADR. The increased prevalence of ADRs among elderly patients could be substantiated by the predominance of somatic diseases and poly-pharmacy in elderly compared to younger patients. [20] Particularly, elderly people are more sensitive to the effects of psychiatric medications and are susceptible to ADRs including cardiac toxicity, confusion, and unwanted sedation.

Causality assessment according to WHO-UMC criteria showed 59% ADRs had probable causality while 40.12% had possible causality and only 0.88% had certain causality. Singh et al. found that most of ADRs were possible and probable. [17] Sengupta et al. found that of 352 events recorded in their study, 327 (92.90%) were “probable” and the rest “possible. [21] Verma et al. found that definite (certain) relationship was established in 30.40% patients while probable in 57.62% and 11.53% ADRs were categorized as possible. [22]

Most cases of weight gain were reported by patients receiving atypical antipsychotics (42 out of 58). Out of total 42 cases of sedation as an adverse effect, 7 cases were noted in patients receiving quetiapine and olanzapine each followed by 8 cases in patients receiving Benzodiazepines (BZD) and 12 cases in patients receiving SSRIs. Headache was reported by 9 patients receiving SSRIs followed by 7 such ADRs in patients receiving atypical antipsychotics. Akathisia and tremor were mostly reported by patients receiving typical antipsychotics. Sexual dysfunction was reported by patients receiving venlafaxine, sertraline, paroxetine or quetiapine.

Sridhar et al. found that atypical antipsychotics followed by selective serotonin reuptake inhibitors (SSRIs) were the most commonly involved psychotropic medications involved in ADRs. [23] Lucca et al. antidepressants were the commonest group of agents implicated in ADRs followed by Antipsychotics. [24]

There is a need for evidence-based practice psychiatry which integrates with day-to-day clinical care. As new evidences are appearing through research, most of the time there is a great delay in its implementation in clinical practice. There is a need to integrate such newer trends which are evidence based and have the potential to improve outcome and overall treatment results. Pharmacogenomics has a useful predictive value in clinical practice. For example, poor metabolizers experience side effects at lower dosages whereas fast metabolizers fail to respond and become treatment resistant. [25] Pharmocogenetic screening is useful in customizing drug treatment. Collaborative model, inter twining of physical and mental disorders should be applied in therapeutics. For example, there is increased incidence of cardiovascular diseases in serious psychiatric disorders such as schizophrenia, bipolar mood disorder, and major depression. [25] Similarly, patients with obesity, diabetes mellitus, hypertension, and dyslipidemia suffer increased rates of psychiatric disorders.[25]

CONCLUSION

As weight gain and gastrointestinal adverse effects were commonly reported in our study, collaborative model, inter twining of physical and mental disorders, for example, increased incidence of cardiovascular diseases in serious psychiatric disorders such as schizophrenia, bipolar mood disorder, and major depression should be applied in therapeutics. Pharmocogenetic screening is also useful in customizing drug treatment. There is a need for evidence-based psychiatry which integrates with day-to-day clinical care. There is a need to integrate newer trends which are evidence based and have the potential to improve outcome and overall treatment results. The study results strongly suggest the need for healthcare professionals to focus more on assessment and reporting of suspected ADRs for generating more evidences for clinician to plan accordingly to reduce the cases of preventable ADRs.

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