Original Article

A Pharmacovigilance Study: Analyzing ADR Reports obtained with conventional and newer atypical antipsychotics in tertiary care teaching hospital of Odisha

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Abstract

Background: Adverse drug reactions (ADRs) are a significant cause of morbidity and mortality, resulting in increased healthcare cost. Association of antipsychotic medications with ADRs is common. Pharmacovigilance can play a vital role in alerting the healthcare and protecting the patients. The present study was carried out to identify 1.the pattern of ADRs reported due to conventional and newer atypical antipsychotics. 2. Causality assessment of ADRs using WHO-UMC scale. 3.Severity assessment of ADRs by modified Hartwig & Siegel scale. **Material and Methods:** This was a cross-sectional study conducted to analyze ADRs reported from the psychiatry department of a tertiary care teaching hospital from December 2021 to April 2024. Ethics committee approval taken vide reference no. 51/IEC SJMCH dated 17.10.2023. **Results:** A total of 77 ADRs were identified from 57 patients. Most of the ADRs were reported from atypical antipsychotics, with risperidone being the commonest drug & tremor (43.07%) was the most common ADR noted. Among conventional antipsychotics haloperidol was the most common drug responsible for ADRs and acute dystonia (34%) was the most common ADR. On causality assessment, 39 ADRs (50.64%) were of "probable" type & 38 ADRs (49.36%) are of "possible" type. **Conclusion:** As the use of Risperidone is more as compared to haloperidol hence more ADRs were reported with atypical antipsychotics than conventional antipsychotics. The present study revealed that the majority of ADRs reported from psychiatry OPD were mild in nature.

Keywords: Adverse drug reaction, Pharmacovigilance, Antipsychotic agents, Risperidone.

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Introduction

Pharmacovigilance (PV) deals with detection, assessment, understanding and prevention of adverse effects associated with drugs. In India the Pharmacovigilance programme is carried out under Pharmacovigilance Programme of India (PVPI), with 1050 adverse drug reaction monitoring centers (AMC)across the country. The different AMCs collect the adverse drug reaction (ADR) reports, then do the causality assessment, analyze, and report the suspected ADR. The objective of PV study is to ensure safe use of medicines by patients. About 0.2 to In the OPD settings the incidence of ADRs range from 5% to 35%.[2] There is close association of psychotropic substances with ADR and has been seen to occur even at usual therapeutic doses used for acute or maintenance phases of psychiatric disorders.[3] Many previous studies have reported a good number of ADRs occurring with antipsychotic drugs. There is also a complete detail description of percentage of ADRs reported with different psychotropic drugs in different published literatures as in Sridhar et al.[2] The conventional antipsychotic drugs like chlorpromazine and haloperidol were used since early 1950's for schizophrenia but there were reports of ADRS like extrapyramidal symptoms and tardive dyskinesia. Because of frequent ADRs encountered with the conventional antipsychotics or the first-generation antipsychotics, the new atypical or second-generation antipsychotics were discovered and were more preferred. The atypical antipsychotics or the second generation antipsychotics act through a number of different receptors like dopaminergic, cholinergic, serotonergic, adrenergic and histamine in comparison to conventional antipsychotics which acts mainly on dopaminergic receptor. The safety and efficacy of these new atypical antipsychotics have been established by large randomized control trials,[3,4] but the atypical antipsychotics are also not without limitations. In these randomized trials there may not be the same comorbid situations in patients that are

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seen in actual clinical practice, and in the randomized trials the trial population is less and when the drugs are used in real field the population mass is more. In many of the studies the patients are also taking other medications like antianxiety, antidepressants or a combination of typical with atypical drugs. So often there is no clear picture of the adverse drug reactions encountered with the typical and atypical antipsychotic drugs. There are reports of metabolic syndrome with altered lipid and glucose metabolism and weight gain with the use of atypical anti psychotics.[5,6] The antipsychotics have been the first line treatment for patients with mental illness but at the same time the clinicians have to be cautious in selecting the particular drug for that particular patient taking into account the patients comorbidities that may be present and weighing the risk and benefit of therapy with the typical or atypical antipsychotic drugs. The right drug for the right patient has to be chosen.[7,8] Hence this study was taken up with an objective to analyze the ADR reports obtained with conventional i.e (chlorpromazine/haloperidol) and atypical antipsychotics (risperidone/olanzapine/quetiapine) and evaluate the severity of ADRs.

Aim & objective-

- To identify the pattern of ADRs reported with conventional and newer atypical antipsychotics.
- Causality assessment of ADRs using WHO-UMC scale
- Severity assessment of ADRs by modified Hartwig & Siegel scale.

Materials and Methods

This is a cross-sectional observational study, conducted by the department of Pharmacology, SJMCH, Puri in collaboration with Department of psychiatry during the period from Nov 2023- April 2024. All the ADR reports associated with conventional and/or Atypical antipsychotics collected by AMC, SJMCH, PURI during the period from December 2021 to April 2024 were analysed.

Ethical Consideration: The study protocol was approved by the Institution Ethical Committee (No.51/IEC, SJMCH, PURI dated 17.10.23).

Inclusion criteria

The ADR reports that included at least one antipsychotic drug was included in the study.

Exclusion criteria

Those reports that were incomplete in any aspect was excluded from the study.

The causality assessment of documented ADR was done by using WHO UMC scale and the severity assessment done by modified Hartwig and Seigel scale.

Statistical analysis: Statistical analysis was done by using excel software. (version 17).

Results

A) Adverse Drug Reactions reported with conventional antipsychotics.

Table 1: Diagnosis of patients who reported adverse drug reactions with conventional antipsychotics.

Psychiatric disorder	Number of patients (%)
Schizophrenia	5 (42)
psychosis	3 (25)
Metabolic encephalopathy	1 (8)
Aggression	1 (8)
Depression	1 (9)
Alcohol withdrawal	1(8)

N.B- Figures in parenthesis are in percentage.

A total of 12 patients were suspected of having at least one ADR. 12 cases of ADR reports obtained from 12 patients were included for analysis. Out of total patients 75% were males & 25% were females.

Schizophrenia (42%) was the most common clinical indication followed by Psychosis (25%). [Table 1]

Table 2: ADRs associated with conventional antipsychotics

Types of ADR	Drug (suspected medication)	Relative frequency of ADRs (%)
Acute dystonia	Haloperidol	4 (33%)
Tremor of hand	Haloperidol	3(25%)
Extra pyramidal symptoms	Haloperidol	1 (8%)
Oculogyric crisis	Haloperidol	1 (8%)
Tardive dyskinesia	Flupentixol (n=2), Trifluoperazine (n=1)	3 (25%)
		Total- 12 ADRs

N.B- Figures in parenthesis are in percentage

Among the ADRs reported with conventional antipsychotics common suspected medication was haloperidol 75% followed by flupentixol 17%. Five different kinds of ADRs were encountered in patients [Table 2].

Acute dystonia (33.33%, n=4) was the commonest ADR followed by tremor of hand (25%, n=3) and other extrapyramidal symptoms, tardive dyskinesia, oculogyric crisis each contributed to 8% (n=1) of ADRS. (Table-2). Trifluoperazine was responsible for tardive dyskinesia in one patient. All ADRs reported with conventional antipsychotics were extrapyramidal reactions.

- Causality assessment using WHO-UMC scale showed that 11 ADRs (92%) belonged to “Probable” category and 1 ADR (8%) belonged to “Possible” category.
- The severity assessment of the ADRs revealed that

ADRs are of Mild category (n=5,60%), moderate (n=7,40%) according to modified Hartwig and Seigel scale.

B) Adverse Drug Reactions reported with atypical antipsychotics.

Table 3: Diagnosis of patients who reported adverse drug reactions with atypical antipsychotics

Psychiatric disorder	Number of patients (%)
Schizophrenia	28 (62)
Bipolar affective disorder	12 (27)
Obsessive compulsive disorder	1 (2)
Psychosis	2(5)
Schizoaffective disorder	1(2)
ADHD	1 (2)

N.B- ADHD-Attention deficit hyperkinetic disorder

A total of 45 patients were suspected of having at least one ADR. 65 ADRs reported from 45 patients were included for analysis. Out of total patients 60% were males & 40% were females. Schizophrenia (62%) was the most common clinical indication followed by bipolar affective disorder (27%) [Table 3]

Table 4: ADRs reported with atypical antipsychotics & their comparative incidence

Type of ADR	Suspected medications	Comparative frequency (%)
Tremor (44%)	Risperidone olanzapine amisulpride aripiprazole	18(28%) 8 (12%) 1 (2%) 1 (2%)
slurring of speech (14%)	Risperidone olanzapine	5(8%) 4 (6%)
Rigidity (10%)	Risperidone olanzapine	5(8%) 1 (2%)
Weight gain (10%)	Olanzapine amisulpride	5 (8%) 1 (2%)
tardive dyskinesia (5%)	Clozapine olanzapine	2(3%) 1 (2%)
Salivation (5%)	olanzapine Risperidone clozapine	1 (2%) 1 (2%) 1(2%)
pedal oedema (4%)	Olanzapine Quetiapine	1(2%) 1(2%)
Tachycardia (2%)	clozapine	1 (2%)
Restlessness (2%)	Aripiprazole	1 (2%)
postural hypotension (1%)	Quetiapine	1 (1%)
Hyperprolactinemia (1%)	Risperidone	1 (1%)
exacerbation of OCD (1%)	clozapine	1 (1%)
Behavioural & psychological symptoms of dementia (1%)	olanzapine	1 (1%)
Akathisia (1%)	risperidone	1 (1%)
Acute dystonia (1%)	Risperidone	1 (1%)

Fifteen different kinds of treatment emergent ADRs were encountered in the patients. Central nervous system was most affected system and tremor (44%) was the most common ADR followed by slurring of speech (14%). Extra pyramidal reactions account for 76% of total ADRs with atypical antipsychotics.

Table 5: Relative frequency of ADRs & individual suspected atypical antipsychotics

Atypical antipsychotics	No. of times the drugs have been prescribed (n=45)	No. of adverse drug reactions (n=65)
risperidone	21 (47)	32(49)
olanzapine	14 (31)	22 (34)
clozapine	5 (11)	5 (8)
amisulpride	2 (5)	2 (3)
Aripiprazole	1 (2)	2 (3)
quetiapine	2 (4)	2 (3)

N.B- Figures in parenthesis are in percentage

Amongst the reported ADR cases with atypical antipsychotics -Risperidone (47%) was the most common suspected medication followed by olanzapine (31%). Less commonly implicated medications amongst the ADR cases were clozapine/quetiapine/aripiprazole/amisulpride, possibly due to comparatively less frequent use of these medications. [Table-5]

Table 6: Causality assessment of ADRs by WHO-UMC scale

Category of ADR	Instances of event (n=65)	Adverse drug reaction	Offending drug (s)
Probable (28)	01	acute dystonia	Risperidone (1)
	01	behavioural & psychological symptoms of dementia	Olanzapine (1)
	01	hypersalivation	Clozapine (1)
	02	pedal oedema	Olanzapine (1) Quetiapine (1)
	01	postural hypotension	Quetiapine (1)
	01	restlessness	Aripiprazole (1)
	01	rigidity	Risperidone (01)
	01	salivation	Olanzapine (1)
	01	slurring of speech	Risperidone (1)
	01	tachycardia	Clozapine (1)
	01	tardive dyskinesia	Olanzapine (1)
	11	Tremor	Risperidone(9),Aripiprazole (1),Olanzapine(1)
	05	Weight gain	Amisulpride (1), Olanzapine (4)
Possible (37)	01	akathisia	Risperidone (1)
	01	exacerbation of OCD	Clozapine (1)
	01	hyperprolactinemia	Risperidone(1)
	05	rigidity	Risperidone,(4) Olanzapine(1)
	01	salivation	Risperidone (1)
	08	slurring of speech	Risperidone (4) olanzapine (04)
	02	tardive dyskinesia	Clozapine (2)
	17	tremor	Risperidone(13),Amisulpride (01),Olanzapine (03)
	01	weight gain	Olanzapine (01)

Causality assessment using WHO-UMC scale revealed that 37 ADRs (57%) belonged to possible category whereas 28 (43%) belonged to Probable category (table-6). As per Hartwig scale 48% ADRs were mild and 52% were moderate. No ADR encountered to be fatal.

Discussion

The present study was an observational study, where we have analyzed the ADRs due to various antipsychotic drugs. The overall incidence rate of ADRs in the present study was found to be 1.07%. This is similar to findings by Shah and Mehta where they reported an incidence rate of 0.67% in psychiatry outpatients.[9]

The evidence from the literature suggests that the incidence of ADRs in psychiatric OPDs in India varies from 6.41% to 41.9%.[10,11] The disparity in the incidence rate reported from different studies might be due to variable study duration and reporting culture. Studies using the spontaneous reporting method generally detect lower incidences of ADRs. In the present study, amongst the reported cases of ADR 63.15% were of male patients and 36.85% were of female patients, where as study by Sridhar et al,[2] shows 49.2% of male patients and 50.7% were female patients. In the current study, the median age of patients with ADRs was found to be more than or equal to 30 years which is similar to study done by Sidhu, et al.[12] In our schizophrenia was the commonest clinical indication for which both typical and atypical antipsychotics were prescribed. Population growth and aging are important factors that have led to a considerable and increasing burden attributable to schizophrenia, particularly in middle-income countries such as India.[13] Amongst the ADR cases reported with conventional antipsychotics. Haloperidol (75%) was the commonest suspected medication followed by Flupentixol (17%). This is possible due to frequent use of Haloperidol followed by Flupentixol among conventional antipsychotics.

This is possibly due to frequent use of haloperidol followed by flupentixol among conventional antipsychotics.[12] different kinds of ADRs encountered in patients. Acute Dystonia (33.33%, n=4) was the commonest ADR followed by tremor of hand (25%, n=3) and other extrapyramidal symptoms i.e tardive dyskinesia, oculogyric crisis each contributed to 8% (n=1) of ADRS.

[Table 2]. Trifluoperazine was responsible for tardive dyskinesia in one patient. Causality assessment using WHO-UMC scale showed that among conventional antipsychotics 11 ADRs (92%) belonged to “Probable” category and 1 ADR (8%) belonged to “Possible” category. ADRs are of Mild category (n=5,60%), moderate (n=7,40%) according to modified Hartwig and Seigel severity assessment scale.

Risperidone (47%) was the most common suspected medication followed by olanzapine (31%) while Clozapine, Amisulpride, Aripiprazole, Quetiapine were less common medications amongst the ADR cases reported with atypical antipsychotics. A study conducted at a tertiary care center in New Delhi had also showed that risperidone (44.71%) was the most commonly implicated antipsychotic.[14] A study pertaining to the drug use pattern of antipsychotics in schizophrenia conducted in the psychiatry outpatient department (OPD) of a tertiary care hospital in Andhra Pradesh showed that olanzapine (37.1%) was the most commonly prescribed drug.[15] Tremor was the most implicated ADR caused by atypical antipsychotics in our study. This is similar to findings obtained by studies who reported tremor as the most commonly noted ADR followed by weight gain.[3,11,16] Many ADR related studies conducted in this area have reported weight gain as one of the most commonly observed ADR in patients taking a certain class of psychotropic medications.[17,18] In meta analysis study evaluating ADR with antipsychotics there are ADR reports of abnormalities of

metabolic & biochemical parameters i.e. impaired blood glucose, dyslipidemia etc. Numerous case series with atypical antipsychotic drugs documented the association of new onset diabetes &diabetic keto acidosis especially with clozapine & olanzapine. But in our study of spontaneous ADR reporting no case of abnormal biochemical parameters is reported. After further interaction with clinicians from psychiatry department it was learnt that they are detecting biochemical abnormalities with antipsychotic medications but are not reporting them to ADR monitoring center, as they are referring the patients to NCD (non communicable disease) clinic. So increase in awareness needs to be created among clinicians to also report drug related abnormal biochemical parameters to ADR monitoring center as this is also an ADR.

Using World Health Organization-Uppsala Monitoring Center (WHO-UMC) criteria, the majority of ADRs due to atypical antipsychotics in our study belonged to the category of possible (57%). The study by Sengupta et.al also found that majority of ADRs were of possible category.[3] Regarding causality assessment, our study had no "certain" cases since the suspected ADRs were mostly of mild to moderate severity and hence usually did not require the

withdrawal of therapy. In cases where de-challenge was done, rechallenge was not attempted with the offending drug. This is in contrast to the Brazilian study where 24cases were found to be "definite" as re -challenge was attempted. The differences in the results of probability scale in various studies may be due to the different scales used for causality assessment or because of individual differences in the interpretation of data. In the present study WHO criteria was preferred over the Naranjo algorithm as its less time consuming and based on clinical judgment. As per Hartwig scale 48% ADRs were mild and 52% were moderate. No ADR encountered to be fatal.

This is similar to other studies where majority of ADRs were of mild nature.[10,11,12] In contrast to the present study, Prajapati et al. reported 65.85% of ADRs to be of the moderate category.[19] Sharma et al. reported two serious cases, while Patel et al. reported one out of five ADRs to be serious.[12,11]

Conclusion

The overall incidence rate of ADRs with antipsychotics in the present study was found to be 1.07%. The evidence from the literature suggests that the incidence of ADRs in psychiatric OPDs in India varies from 6.41% to 41.9%.[10,11,19] In our study most common ADR with both typical & atypical antipsychotics was extrapyramidal reactions. But Acute dystonia was the commonest extrapyramidal symptoms with conventional antipsychotics & tremor was the commonest ADR with atypical antipsychotics. Haloperidol was the commonest suspected medication among conventional antipsychotics & Risperidone was the commonest medication among atypical antipsychotics, suggesting more tendency of extrapyramidal symptoms even with atypical antipsychotics. There is less reporting of biochemical parameter abnormalities i.e. blood sugar & serum lipid etc in our study as they are being only referred to NCD clinics without reporting of these abnormalities to ADR monitoring centre. This indicates increase in awareness must be created among the clinician to report abnormal biochemical parameters with antipsychotics.

Conclusion & Limitations of study

It is a retrospective analysis of ADR reports obtained from Psychiatry department. There is no follow up of the patients prospectively taking various antipsychotic medications & find out their ADRs. This is required to obtain a clearcut picture on ADR status of antipsychotic medications which can be taken up in subsequent studies.

The way forward from the above study-

1. There is inadequate reports of metabolic & biochemical ADRs in our study as a result of referral of these ADRs by psychiatrist to NCD clinics without reporting them to AMC. So awareness campaign may be done by AMCs in psychiatry department for detection, assessing, understanding & reporting of metabolic & biochemical ADRs with antipsychotics.
2. This study also suggests the need of a drug utilization pattern of antipsychotic medication in our tertiary care centre to find out whether the maximum number of ADRs reported with risperidone (among atypical antipsychotics) are due to more use of risperidone at this tertiary care hospital or risperidone (among atypical antipsychotics) have relatively higher incidence of ADRs in our patients

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Conflicts of interest

There are no conflicts of interest.

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