

Adverse Drug Reaction Pattern of Anti Psychotic Drugs Prescribed In Psychiatry Out-Patient Department in a Tertiary Care Hospital

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Abstract

OBJECTIVE:

To study the pattern of adverse drug reactions of Anti psychotic drugs in patients attending the Psychiatry out-patient department at Rajiv Gandhi Government General Hospital .

METHODS:

400 patients attending psychiatry OPD were enrolled in the study .Duration of study was 2 months .Adverse drug reactions of Anti psychotic drugs were documented .Causality assessment of ADRs was done using WHO Causality assessment score. Severity assessment was done using Modified Hartwig Siegel severity assessment scale.

RESULTS:

Most of the patients were in the age group of 31-40 years.Males constituted 60% and females 40% of test population. Risperidone was the most commonly prescribed Anti psychotic drug. Among 400 patients, 377 patients developed adverse drug reaction (94%).Sedation was the most common adverse drug reactions encountered.Extrapyramidal symptoms (Tremors , Dystonia) were more common with Haloperidol and Chlorpromazine whereas weight gain was seen only with Risperidone. Most of the ADRs were mild and comes under probable category.

CONCLUSION:

Risperidone was the most commonly prescribed Anti psychotic drug.Sedation was the most common adverse drug reaction encountered. Most of ADRs were mild and comes under Probable category of WHO causality assessment scale.

Keywords: adverse drug reactions , anti psychotic drugs, causality, severity

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I. Introduction

Adverse Drug Reaction (ADR) is defined by WHO, "As a response which is noxious and unintended and which occurs at doses normally used in humans for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function." [1].

In this era of Drug explosion, numerous drugs are hitting the market day by day. As innovation in medicine continues and new drugs are being developed, there is always a potential for the occurrence of increasing number of ADRs [2].

As drugs act by interfering with molecular and cellular function in our body.They have the risk of producing undesirable side effects [3]. Management of chronic diseases like Diabetes, hypertension and psychiatric diseases require prescription of combination of drugs .There is always high potential of developing adverse drug effects due to drug interactions.

Every physician must have adequate knowledge on Adverse drug reaction pattern of various drugs so that the prescriptions are rational and are assured of safety for the patients. 10-15% of patients receiving medications suffer from Adverse drug reactions. The incidence of serious ADRs is 6.7 % [4].Management of ADR is very costly and is of major economic burden.

Psychiatric disorders involve disturbances in mood, affect and socialization.The Psychiatric illnesses are of importance because they are chronic in nature and there are more chances of poor compliance in taking medications.[5].

Adverse drug reactions associated with anti psychotic drugs can affect the management of psychiatric diseases as they affect the compliance [6,7].Monitoring Adverse Drug Reactions in Psychiatry helps in alerting physicians about the possibility and circumstances of Adverse events [8].

In India, Adverse drug monitoring activities are still in preliminary stage and there are very few reports available on the ADR profile of anti psychotic drugs . Hence this study was undertaken to evaluate the ADR pattern of Anti psychotic drugs .

II. Materials And Methods

OBJECTIVE:

To study the pattern of adverse drug reactions of anti psychotic drugs in patients attending psychiatry out-patient department in a tertiary care teaching hospital .

STUDY DESIGN: Prospective Observational study

STUDY POPULATION: Adult patients attending psychiatry outpatient department taking antipsychotic drugs.

STUDY CENTRE: Department of Psychiatry, Madras Medical College & Rajiv Gandhi Government General Hospital, Chennai.

SAMPLE SIZE: 400

STUDY DURATION: 2 months.

INCLUSION CRITERIA:

- Age :19-70years
- Gender: both male and female
- Patients on anti psychotic drugs.
- Patients willing to give informed consent.

EXCLUSION CRITERIA:

- Patients not willing to give informed consent.
- Patients on other drugs(anti depressants,anti epileptics,sedatives,hypnotics) along with Antipsychotics

STUDY PROCEDURE:

The study was conducted after getting approval from Institutional Ethics committee.

Patients with chronic psychiatric illness receiving treatment with antipsychotic drugs at out-patient department of Psychiatry were explained about the study purpose in their local language.Written Informed consent was obtained from those who are willing to participate in the study. If the patient could not understand the purpose of the study, the same was explained to their attenders /relatives and written informed consent was obtained from them.

The following parameters were recorded :

- Age
- Gender
- Anti psychotic drugs prescribed
- Duration of Treatment
- Adverse drug reaction pattern (Incidence and Severity)

Causality assessment of the ADRs was done by establishing the temporal association of drug use with ADRs using WHO causality assessment scale. Severity was assessed using Modified Hartwig Siegel severity assessment scale.

III. Results

In Rajiv Gandhi Government General Hospital, Anti psychotic drugs were issued once in two weeks to the patients in psychiatry OPD.

The anti psychotic drugs prescribed in the Out-Patient Department of Psychiatry were Chlorpromazine, Haloperidol and Risperidone.754 prescriptions were screened. 400 prescriptions which fulfilled the inclusion criteria were analysed. Data was entered into Excel spreadsheet and descriptive statistics was used to analyse the data. Most of the patients were in the age group of 31-40 years .60% were males and 40 % were females.Male to Female ratio was 1.3:1.

Table 1: AGE DISTRIBUTION OF THE PATIENTS

AGE GROUP	NUMBER OF PATIENTS	PERCENTAGE
<20 yrs	20	5%
21-30yrs	98	24%
31-40 yrs	129	32%
41-50 yrs	79	20%
51-60 yrs	41	10%
61-70 yrs	33	9%
TOTAL	400	100%

Table:1 shows the age distribution of the patients.Most of the patients were in the age group of 31-40 years

Table 2: PRESCRIBING PATTERN OF ANTI-PSYCHOTICS

ANTI-PSYCHOTIC DRUGS	NUMBER OF PRESCRIPTIONS	PERCENTAGE
CHLORPROMAZINE	124	31%
HALOPERIDOL	119	29%
RISPERIDONE	157	40%

Table: 2 shows the Prescribing pattern of anti-psychotics. Risperidone was the most commonly prescribed anti-psychotic drug .

Table 3: PERCENTAGE OF PATIENTS WITH ADRS

	NUMBER OF PATIENTS	PERCENTAGE
PATIENTS WITH ADRs	236	59%
PATIENTS WITHOUT ADRs	164	41%
TOTAL	400	100%

Table 3 shows percentage of patients with ADRs.

Table 4: ADVERSE DRUG REACTION PATTERN OF RISPERIDONE

ADVERSE DRUG REACTIONS	NO.OF PATIENTS	PERCENTAGE
SEDATION	30	33%
WEIGHT GAIN	13	14%
MEMORY LOSS	25	27%
DRY MOUTH	16	19%
EPS	5	6%
GALACTORRHOEA	2	1%
TOTAL	91	100%

Table 4 represents Adverse drug reaction pattern of Risperidone.Sedation was the most common ADR (33%) followed by Memory loss (27%),dry mouth (19%) ,weight gain (14%) EPS (6%) and Galactorrhoea (1%)

Table 5: ADVERSE DRUG REACTIONS PATTERN OF CHLORPROMAZINE

ADVERSE EFFECTS	NO.OF PATIENTS	PERCENTAGE
SEDATION	29	34%
CONSTIPATION	12	14%
MEMORY LOSS	18	21%
EXTRA PYRAMIDAL SYMPTOMS	15	18%
DRY MOUTH	11	13%
TOTAL	85	100%

Table5 represents Adverse drug reactions pattern of chlorpromazine. Sedation was the most common ADR (34%) followed by memory loss (21%) , EPS (18%) ,constipation (14%) and dry mouth (13%)

Table 6: PATTERN OF ADVERSE DRUG REACTIONS OF HALOPERIDOL

ADVERSE DRUG REACTIONS	NO.OF PATIENTS	PERCENTAGE
SEDATION	21	30%
TREMORS	19	28%
MEMORY LOSS	15	22%
DYSTONIA	7	10%
AMENORRHOEA	4	6%
GALACTORRHOEA	3	4%
TOTAL	69	100%

Table 7 represents Adverse drug reaction pattern of Haloperidol. Sedation was the most common ADR (30%) followed by tremors (28%), memory loss (22%), dystonia (10%), Amenorrhoea (6%) and Galactorrhoea (4%)

Causality assessment of Adverse drug reactions:

53% ADRs were under Probable category, 31% ADRs under Possible category and 16% ADRs were categorised as Certain

Table 8: Causality Assessment of Adverse drug reactions

ASSESSMENT CATEGORY	NO.OF PATIENTS	PERCENTAGE
CERTAIN	59	16%
PROBABLE	198	53%
POSSIBLE	120	31%
TOTAL	377	100%

Table 8 represents causality assessment of Adverse drug reactions

Severity assessment of ADRs:

95% of Adverse drug reactions were categorised as mild, 4% as moderate and 1% as severe (required hospital admission)

Table 9 : Severity assessment of Adverse drug reactions

ASSESSMENT CATEGORY	NO.OF PATIENTS	PERCENTAGE
MILD	358	95%
MODERATE	17	4%
SEVERE	2	1%
TOTAL	377	100%

Table 9 represents Severity assessment of ADRs

IV. Discussion

Incidence of occurrence of psychiatric disorders are increasing nowadays and are associated with increased morbidity and mortality. As a result of their chronic nature, they have a major contribution to the burden of illness worldwide.

Extra pyramidal side effects like dystonia and parkinsonism are more commonly seen with typical antipsychotics because of their potent D2 receptor blocking property and hence Atypical antipsychotics are commonly used in Psychiatry OPD nowadays. However, they carry the risk of metabolic abnormalities and weight gain [9].

In our study, Among 400 patients who were on antipsychotic drugs, 236 patients developed at least one adverse drug reaction (59%).

Risperidone was the most commonly prescribed Anti psychotic drug. This correlates with the results of study conducted by Ilyaz, Md et al [10].

Sedation was the most common adverse drug reaction encountered.

Extrapyramidal symptoms were more common in patients taking Haloperidol and Chlorpromazine whereas weight gain was more frequently encountered in patients taking Risperidone.

About 53% of ADR were under Probable category of WHO causality assessment scale. Most of the ADRs were mild which required only dose reduction .

The adverse drug reaction pattern reported in our study correlates with the results of studies conducted by Gairik Sengupta [11] and Kingshuk Lahon [12]

Our study has given an insight about the ADR pattern of anti psychotic drugs in a tertiary care teaching hospital .Constant monitoring and detecting ADRs and adjusting the doses of the drugs accordingly can make the management of Psychiatric diseases safer and more effective.

V. Conclusion

Risperidone was the most commonly prescribed Anti psychotic drug. Sedation was the most common adverse drug reaction encountered. Most of ADRs were mild and fell under Probable category of WHO causality assessment scale.

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