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To Study the Pattern of Adverse Drug Reaction of Antipsychotic Drugs in a Tertiary Care Hospital of Assam

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Abstract:
Objective: 1) To record the various types of adverse drug reactions related to the antipsychotic drugs.
2) To find out the causality, severity and preventability of adverse drug reaction related to the antipsychotic drugs.
Methodology: It is a prospective, cross-sectional, observational open label study carried out for a period of six months, from 1/07/2014 to 31/12/2014, after getting approval from human ethical committee, among the indoor patients of the department of Psychiatry, Assam Medical College and Hospital.
Results: Total 359 patients were screened for this study, out of which 197 were males and 162 were females. Out of 359 patients, 33 patients(9.19%) were detected with 12 types of ADRs. Incidence of ADRs was higher in males (22 patients; 66.67%) than female (11 patients; 33.33%).12 different types of ADRs were detected among which TREMOR (36.36%) was commonest. Out of 8 antipsychotic drugs causing ADRs, OLANZAPINE (12.8%) was commonest followed by CLOZAPINE.Majority of ADRs were assessed as PROBABLE(84.85%) according to WHO-UMC causality assessment system.Most of the ADRs were assessed as NOT PREVENTABLE (57.58%) according to SHUMOCK AND THRONTON SCALE.Majority of ADRs were assessed as MODERATE(57.57%) and rest were MILD(42.43%) according to HARTWIG'S severity assessment scale.
Conclusion: To conclude, our study shows TREMOR was the commonest ADR detected and OLANZAPINE was the commonest drug causing ADRs. Majority of ADRs were assessed as PROBABLE according to WHO-UMC causality assessment system;NOT PREVENTABLE according to SHUMOCK AND THRONTON SCALE and MODERATE according to HARTWIG'S severity assessment scale.
Keywords: Adverse drug reaction, Antipsychotics, pharmacovigilance, Tremor, Olanzapine.

Introduction:

According to WHO, adverse drug reaction is defined 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" [1]. Antipsychotics are a class of agents which are able to reduce psychotic symptoms in a wide range of conditions like schizophrenia, bipolar disorder, psychotic depression, senile psychosis, various organic psychosis and drug induced psychosis [2]. Antipsychotic drugs are plentiful in numbers and their use is increasing day by day. These drugs are capable of causing numbers of

ADRs[3,4], some of which may be fatal[5]. ADRs associated with antipsychotic drugs can lead to non-compliance and,or discontinuation of therapy [6]. Pharmacovigilance in psychiatry units can play a vital role in detecting ADRs and alerting physicians to the possibility, circumstances and consequences of such events, thereby protecting the user population from avoidable harm.

In India, pharmacovigilance activities are still in nascent stage and there are only fewreports available on the profile of antipsychotic drugs. This leads us to evaluate the ADR profile of antipsychotic drugs used in a tertiary care hospital in Assam.

Materials and Methods:

Study Design:

It is a prospective, cross-sectional, open label study carried out for a period of six months, from 1/07/2014 to 31/12/2014, after getting approval from human ethical committee.

Study Population:

Depends on the numbers of patients reporting the adverse drug events during the study period.

Place of Study:

Indoor patients of psychiatry ward of Assam Medical College and Hospital, Dibrugarh.

Inclusion Criteria:

1. All patients receiving antipsychotic drugs irrespective of diagnosis.
2. Patients receiving only one antipsychotic drug.

Exclusion Criteria:

1. Patients with substance abuse.
2. Patients not accompanied with family care givers.
3. Pregnant women.
4. Children <12 years.

A prior consent was taken from the attendants.

Recording Of Data:

All the data's were recorded in the WHO adverse drug event forms. This was done via spontaneous reporting of adverse drug event by a post graduate student of department of psychiatry as being assigned.

Simple statistical methods were used to determine:-

1. All different adverse drug reactions caused by antipsychotics.
2. Most common antipsychotic drug associated with adverse drug reactions.
3. Causality of adverse drug reactions was assessed as per WHO-UMC CAUSALITY ASSESSMENT SYSTEM.[7]
4. Severity of the adverse event was assessed by HARTWIG'S SCALE.[1]
5. Preventability of adverse drug reaction was assessed by SHUMOCK AND THRONTON SCALE[8]

Results:

Screening of Samples:-Total 359 patients were screened for this study, out of which 197 were males and 162 were females.

Number of Patients ADRs Identified:-Out of 359 patients, 33 patients(9.19%) were detected with 12 types of ADRs. Incidence of ADRs was higher in males (22 patients; 66.67%) than female(11 patients; 33.33%).

Types of ADR Identified:- 12 different types of ADRs were detected among which TREMOR (36.36%) was commonest.

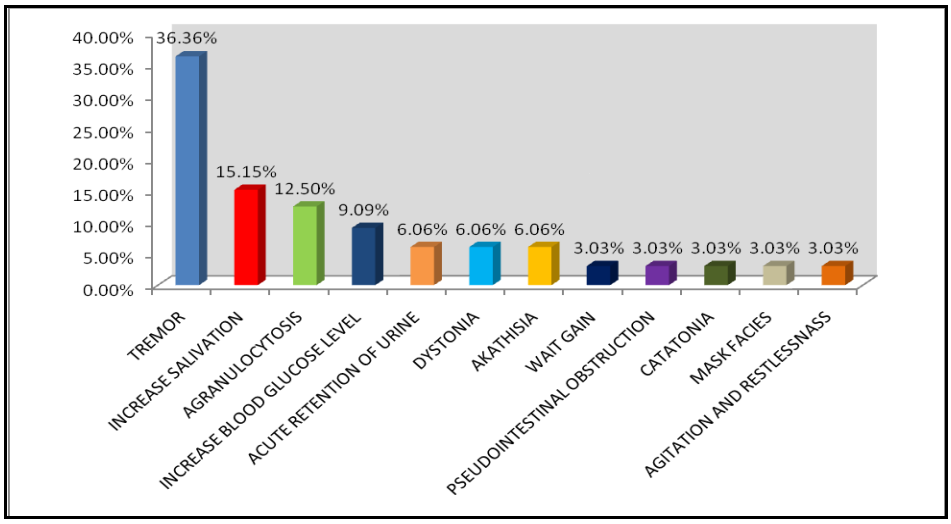


Fig. 1. Shows incidence of ADRs caused by antipsychotics

Most common drug associated with ADRs was OLANZAPINE

Table.1. Drugs associated with ADRs.

DRUG USED	NO.S OF PATIENTS	NO.S OF ADRs	PERCENTAGE
OLAZAPINE	117	15	12.8%
CLOZAPINE	78	8	10.25%
CHLORPROMAZINE	11	1	9.09%
BONANSERINE	11	1	9.09%
HALOPERIDOL	34	3	8.82%
RISPERIDONE	47	3	6.38%
CLONAZEPAM	23	1	4.34%
QUETIAPINE	38	1	2.63%

Out of 8 antipsychotic drugs causing ADRs ,OLANZAPINE (12.8%) was commonest followed by CLOZAPINE.

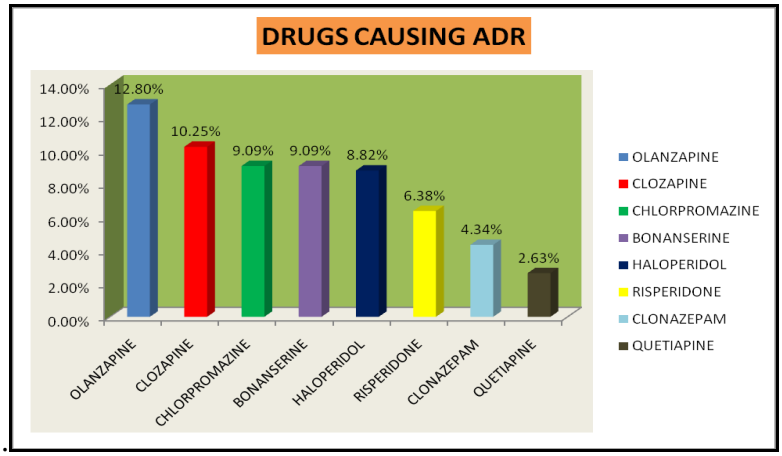
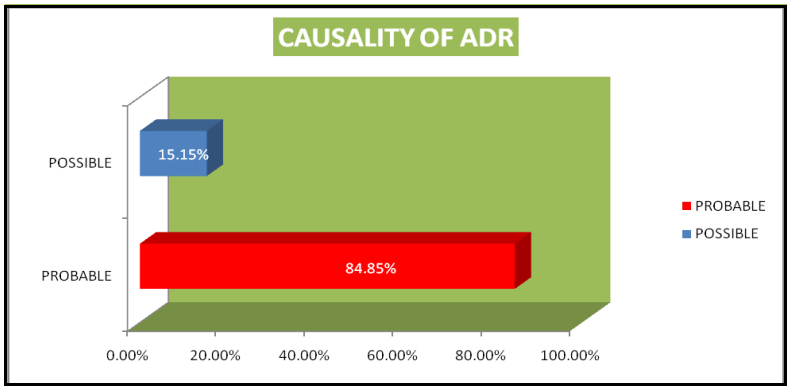


Fig.2. Shows drugs causing ADRs

Causality of ADR:-Majority of ADRs were assessed as PROBABLE(84.85%) according to WHO-UMC causality assessment system.



Preventibility of ADR:-Most of the ADRs were assessed as NOT PREVENTABLE (57.58%) according to SHUMOCK AND THRONTON SCALE.

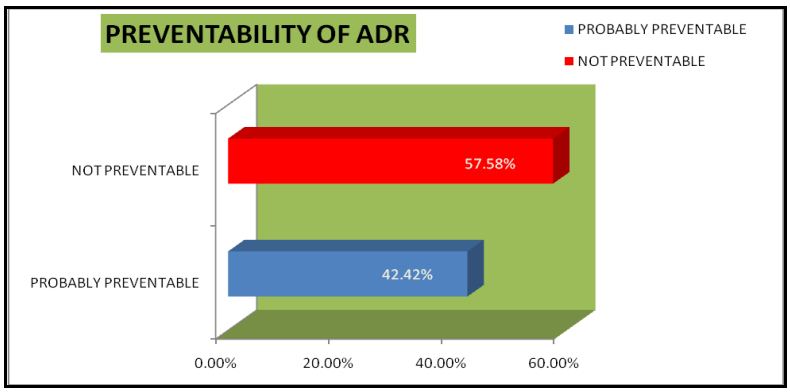


Fig.3. Shows Preventability of ADRs.

Discussion:

As per the NATIONAL HEALTH SERVICES regarding the use of antipsychotics as first line agents, it is said that first and second generation antipsychotics are equally efficacious but when no consensus is reached between their to start the second generation ones. Various studies have seen that the second generation antipsychotics were having fewer adverse effects and though both groups were equally efficacious [9] Thus, it is seen that use of second generation antipsychotics are more than first generation.

- This prospective study highlights the incidence and pattern of ADRs of antipsychotics in North-Eastern part of the country.

- In our study we found incidence of ADRs was 9.19%. Olanzapine was the frequently used drug having highest numbers of ADRs(45.45%) and Tremor was the commonest ADR(36.36%). A similar study was done in IPGMER, Kolkata in 2011, reported incidence of ADRs was 17.25%; Olanzapine was the commonest drug causing ADRs(31.82%) and Tremor was the commonest ADR(19.60%).[10]
- Regarding causality assessment, our study had no "certain" causes since ADRs reported were mild to moderate. In cases where dechallenge was done, rechallenge was not attempted with the offending drug. This is in contrast to a Brazilian study where 23 cases were found to be "definite" after rechallenge was attempted.(11)
- Using modified SHUMOCK AND THRONTON CRITERIA, ADRs like Tremor, Aathisia, Dystonia etc. were assessed as probably preventable(42.42%) and ADRs like Agranulocytosis, Increase blood sugar level etc. were assessed as not preventable (57.58%).
- Regarding the interesting ADRs noted, Haloperidol induced pseudo intestinal obstruction which was marked as possible because rechallenge was not done.[12]

Conclusion:

Nowadays antipsychotics are frequently used drugs and their ADRs are plentiful, which leads to non-compliance, behavioral changes and discontinuation of therapy. Our study provides a representative idea of prescribing pattern and ADRs likely to be occurred in North-Eastern region of India. A constant pharma covigilance in detecting ADRs and subsequent dose adjustments can make the antipsychotic drug therapy safer, more effective and have more patient compliance.

To conclude, an antipsychotic drug database built upon the basis of such studies conducted across multiple centers, through active collaboration of psychiatrists and pharmacologists can be a high yielding long term goal in Indian context.

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