

Pattern of Adverse Drug Reactions Due to Antipsychotic Drugs in a Regional Adverse Drug Reaction Monitoring Centre in South India

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Abstract: Psychosis is a mental disorder in which the patient loses contact with reality and surroundings. These disorders are increasing day by day and so the patients are regularly treated with antipsychotic drugs. These drugs are also causing severe adverse effects causing decreased quality of life and economical burden. So the pharmacovigilance studies will be useful to identify and prevent these adverse drug reactions (ADRs). Hence the objective of this study is to identify ADRs to antipsychotic drugs reported to ADR monitoring centre in a tertiary care centre. Among them, the commonest Adverse drug reactions (ADRs) reported are extrapyramidal symptoms, diabetes, salivation, and constipation and the common drugs causing these ADRs are resperidone and olanzapine.

Keywords: Adverse drug reaction (ADR), pharmacovigilance programme of india (PvPI), ADR monitoring centre (AMC),

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I. Introduction

Peace of mind is a way of life and when it is lost, man behaves abnormally which is called mental disorder or psychiatric disease. They also include depression, excessive anxiety and psychosis, loss of contact with society and finally suicidal tendencies. In the present hitec days, psychiatric problems are increasing that every 6th person in india needs mental help [1]. Global burden is that 4 out of 10 causes of morbidity is psychiatric origin[2]. There is iceberg phenomenon in this that many cases are not seeking medical help due to various reasons and so the burden may be still high. Those who sought medical assistance, they have a great help with antipsychotic drugs and counselling. The therapy of psychosis is a multidirectional including very effective drugs in these days. The antipsychotic drugs should be used life long many times which causes many adverse drug reactions (ADR) [3].

An adverse drug reaction 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"[4].

Among antipsychotics, older antipsychotics have a higher incidence of ADRs compared to atypical antipsychotics.[5]. Many times patient gets confused about his symptoms whether they are due to his disease or due to the ADRs of antipsychotic drugs. Hence the ADRs need to be recorded. So WHO has identified the importance of Pharmacovigilance which is the science dealing with detecting, assessing and preventing ADRs [6].

The pharmacovigilance has great importance in psychiatric patients as it can protect the patients from preventable harm and alert the physicians regarding the possibility of those events in the near future.[7] The pharmacovigilance in India needs to be strengthened due to the scarcity of data available related to ADRs especially with psychotropic drugs.[8] and also it has a great potential towards safeguarding the patients. There is an immense need to strengthen these activities and develop ADR profile of psychotropic drugs.[9] However, in India only few studies have looked into ADR monitoring among psychiatric patients.[10-14]

Hence the National Pharmacovigilance Programme of India (PvPI) was started with the objectives of monitoring the safety of drugs and creation of ADR database for the Indian population [15]. In this regard this particular observational study was taken up by analysing the pattern and occurrence of ADRs to antipsychotic drugs reported to ADR monitoring centre at tertiary care teaching hospital to identify and analyse the extent of occurrence of ADRs, its causality, severity, and predictability.

II. Materials and Methods

This is an observational study carried out at the regional ADR monitoring centre(AMC), Government General Hospital, Guntur, Andhra Pradesh, India. The study was done after obtaining approval of the Institutional Ethics committee. All the Adverse Drug Reactions (ADRs) which were reported to the regional AMC, under pharmacovigilance programme of India for a period of 1 year, from Jan 2014 to Dec 2014 were taken for the study. Among them only ADRs due to antipsychotic drugs were included in the study. The causality assessment is done with WHO-UMC scale

III. Results

Table no.1: Division of ADRs reported to the AMC

ADRs reported in 1year	Number
over all ADRs reported	246
ADRs reported from antipsychotropic drugs	17
Percentage of ADRs reported from antipsychotropic drugs	6.9%

Figure no.:1

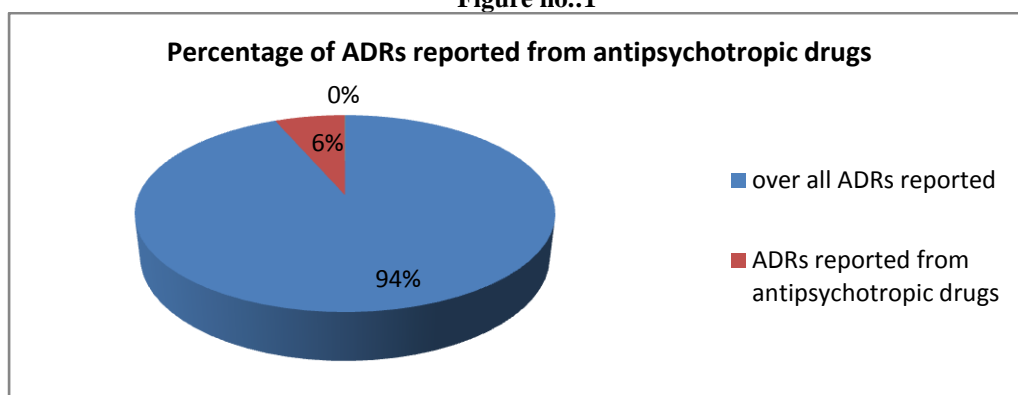


Table no.02: Gender wise distribution

Males	5	31%
Females	11	69%

Figure-02

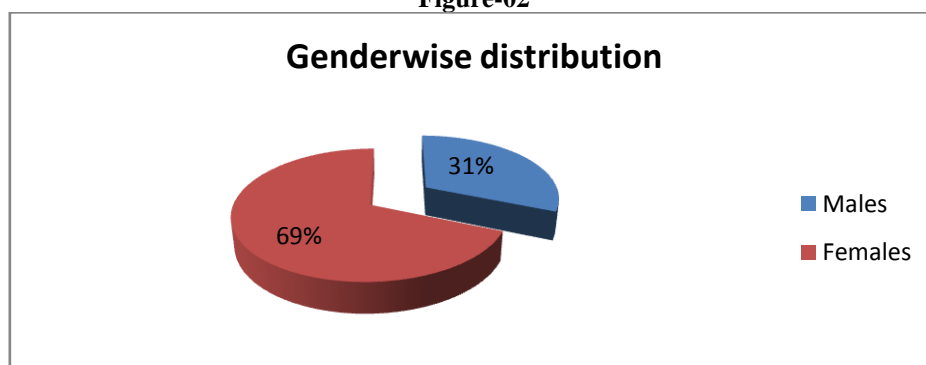


Table no-03 Age wise distribution

Age range in years	No. of cases	Percentage%
0-19years	1	6.25%
20-39 years	8	50%
40-59 years	6	37.5%
>60 years	1	6.25%

Figure no-03

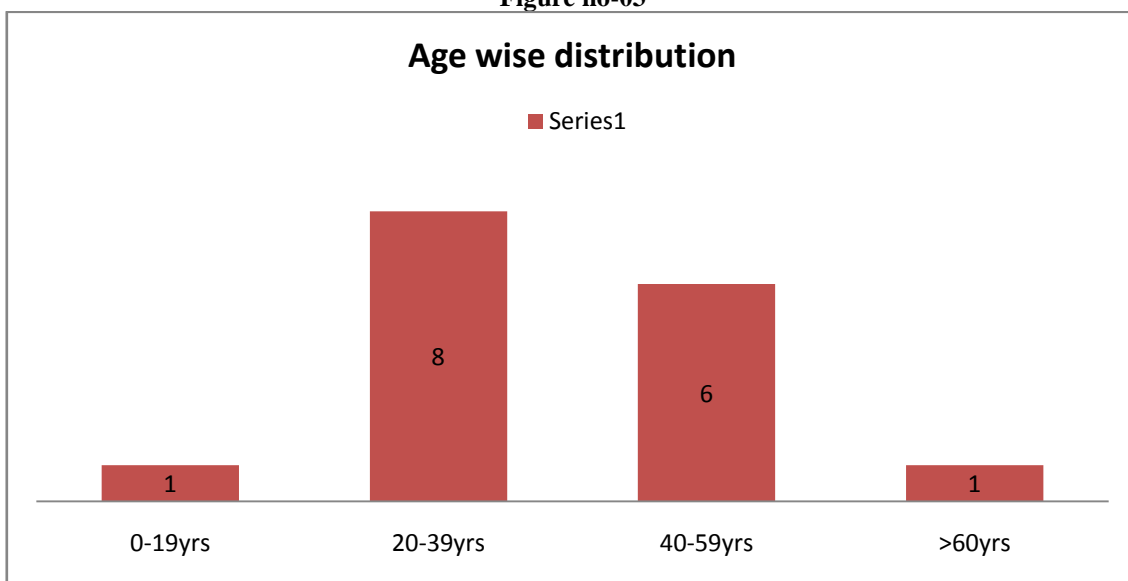


Table no.04 pattern of ADRs reported

ADRs reported	No.of cases	Percentage%
Hypersalivation	2	12.5%
Xerostomia	1	6.25%
Extrapyramidal disorder	5	31.25%
Pedal oedema	1	6.25%
Hyperglycaemia	4	25%
Akathisia	1	6.25%
Constipation	2	12.5%
Asthenia	1	6.25%
Hyperlacrimation	1	6.25%
Dystonia	2	12.5%

Figure No.04

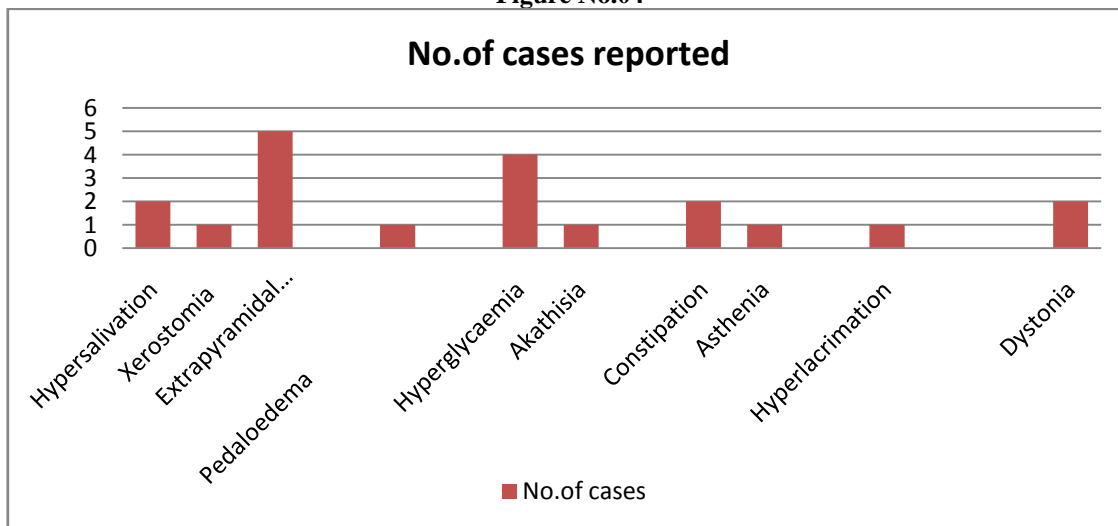
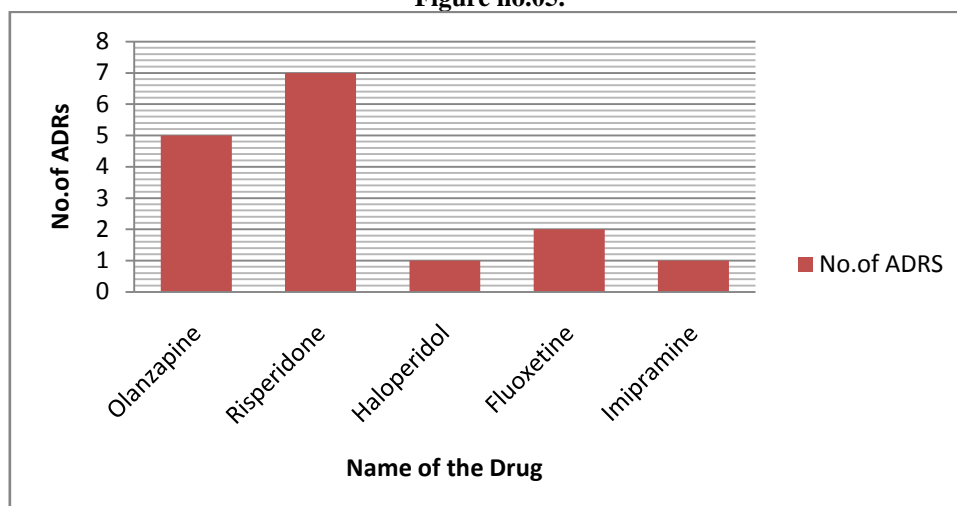


Table no.05

Drug with ADR	No.of ADRS	Percentage%
Olanzapine	5	31.25%
Risperidone	7	43.75%
Haloperidol	1	6.25%
Fluoxetine	2	12.5%
Imipramine	1	6.25%

Figure no.05.



IV. Discussion

This study done in a tertiary care teaching hospital with established pharmacovigilance centre by pharmacovigilance programme of India (PvPI) has showed the pattern of ADRs due to antipsychotic drugs. It is well established that all antipsychotics have side effects and an attempt is made to identify the reporting of ADRs into the pharmacovigilance centre. The total contribution of India in adverse drug reaction information in monitoring is only 1% in global data, which shows under-reporting [16] and/ or under-detection as health care professionals are not so aware about pharmacovigilance or do not have adequate knowledge about ADR monitoring and reporting, due to which the exact incidence of ADRs is still unknown [17,18].

In this study, ADRs due to antipsychotic drugs constitute 6.9% of the total ADRs reported to the ADR monitoring centre, during the 1 year study period where as Pritom Kurmi et al reported 9.19% [19]. It was found that majority of patients were females (69%), which is consistent with the findings in a study by Singh et al in 2017 [20]. However it is contrary to the study by Pritom Kurmi et al where male preponderance was seen by 66.69% [19]. Most of the ADRs were reported among patients in the age group 20-39 years (50%) which is consistent with viswanathan MT et al [21].

Among the ADRs, the extrapyramidal disorders were the commonest ADR (31.25%) which is consistent with findings in a study by Pritom Kurmi et al [19] in which it is reported as 36.36% and the next commonest ADR is hyperglycemia (25%) which is contrary with findings of Pritom Kurmi et al where it is seen as 9.09% [19]. The hypersalivation is reported in 12.5% cases which is also consistent with findings of viswanathan MT et al [21] in which he reported as 19% and also consistent with Pritom Kurmi et al [19] which is reported as 15.15%, the constipation is reported in 12.5% cases which is contrary of viswanathan MT et al [21] in which he reported as 4%. The pedal edema is reported in 6.25% cases in this study whereas viswanathan MT et al [21] reported it as 4% which is nearly consistent.

Among the drugs causing ADRs, Risperidone (43.75%) was reported as the commonest drug responsible for ADRs which is consistent with that reported by viswanathan MT et al [21] as 57.14% and the other drugs consecutively responsible for the ADRs are Olanzapine (31.25%), Haloperidol (6.25%), Fluoxetine (12.5%) Imipramine (6.25%).

V. Conclusion

As the burden of psychotic problems are increasing largely and the antipsychotic drugs are extremely beneficial in their treatment. But ADRs associated with antipsychotic drugs usage should be given utmost importance in notifying. ADRs can be better avoided or prevented only by active functioning of ADR monitoring and reporting centres under pharmacovigilance programme of India. So awareness of pharmacovigilance among the health care professionals can bring down the ADR incidence due to antipsychotic drugs and there by decrease the suffering of patients due to ADRs in a developing country like India.

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