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ADVERSE DRUG REACTION AMONG PSYCHIATRIC INPATIENTS: A LONGITUDINAL OBSERVATIONAL STUDY

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ABSTRACT

Background: Adverse drug reactions (ADRs) are the prime determinants of non-adherence to drugs. In psychiatric care even, the normal doses can elicit severe adverse responses, that may adversely affect the outcome of treatment. Materials & methods: This was a Longitudinal observational study conducted during august 2020 in male ward of psychiatric hospital. The causality assessment of documented ADRs was done using Naranjo scale, and WHO-The Uppsala Monitoring Centre probability scale, severity was assessed using Hartwig et al. scale, and preventability assessment using Modified Schumock and Thornton's Scale. Out of 81 patients, 79 patients were reported with ADR and a total of 79 ADRs were identified. The most common were acidity, gastritis, somnolence. Based on the causality assessments as per Naranjo Algorithm most of the ADRs were found to be probable and that of WHO-UMC scale were certain. According to severity assessment done using modified Hartweig & Seigel scale majority of the ADRs were moderate and as per Schumock Thronton scale for preventability more than half of the ADRs were definitely preventable. Conclusion: This study provides an insight into ADR pattern among psychiatric in-patients. A high frequency of ADRs were seen in the inpatients of psychiatry settings, particularly of moderate nature and most likely preventable sorts. Psychiatric drugs are more likely to develop ADRs when to compared to anti-epileptics and sedative drugs. Continuous monitoring and assessment of patients using psychiatric drugs may help to improve patient safety.

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INTRODUCTION

Adverse Drug Reactions (ADRs) are a reason for morbidity and mortality in both inpatients and outpatients, leading to additional expenditure in medical bills and they are very common with psychotropic medications. [1] ADRS were strong predictors of discontinuation. [2] Due to the chronicity and relapsing nature of psychiatric disorders, most guidelines recommend that treatment should be continued for several months or years.[3] Psychiatric drugs are frequently associated with ADRs. The treatment is mostly enduring and non-adherence is usual with prolonged treatment. [4]

In psychiatric care even the normal doses used in the management of acute and maintenance phase of psychiatric disorders can elicit severe adverse responses. This can have a negative impact on the quality of life, therapeutic outcome, adherence etc. The pattern and nature are based on the drug or class. [5,6] Many studies indicate that the incidence rate of ADR is greater than 50% in India. [7]

At times, these ADRs can be fatal or disabling. It is important for psychiatrists to be aware of the processes involved in identifying and reporting ADRs, especially those that are new or unrecognized. These processes form the basis for the medical discipline of pharmacovigilance. Most adverse drug events, even if not life-threatening, can be distressing and troublesome to patients. Reporting these events could help in building trust between patients and physicians. The practice of regular reporting can also lead to earlier identification of problems, which can improve patient compliance and quality of life. Pharmacovigilance can play a crucial role in alerting health care providers from possible ADRs. [8] But in India pharmacovigilance is not well-established and reporting rate is not so much as compared to other developed countries. This study was aimed to identify the ADR occurred in psychiatry department inpatients of a secondary care hospital.

MATERIALS AND METHODS

The study was conducted at a psychiatry specialized hospital in Kerala. This was a Longitudinal observational study conducted during august 2020 in male ward. Patients of all age groups and male gender, diagnosed with any psychiatric disorder and receiving psychotropic medications and admitted in the psychiatry department of the site were monitored for ADRs and included in the study.

During the study period, the details of 81 patients in whom ADRs were noticed by the treating psychiatrist, reported by the patient or their caretakers, and by other healthcare professional during daily rounds were documented by the clinical pharmacist. The required data was collected from the patient case files as well as from the patients themselves and their caretakers if required and was entered in the designed ADR reporting and documentation form, which includes various details such as demographic information, disease, and other relevant information.

The causality assessment of documented ADRs was done using Naranjo scale, and WHO-The Uppsala Monitoring Centre probability scale, severity was assessed using Hartwig et al. scale, and preventability assessment using Modified Schumock and Thornton's Scale.

RESULTS

A total of 81 male patients were enrolled in the study with mean age of 42(±13). Distribution pattern of disease and drugs were picturized on figure 1 and 2.

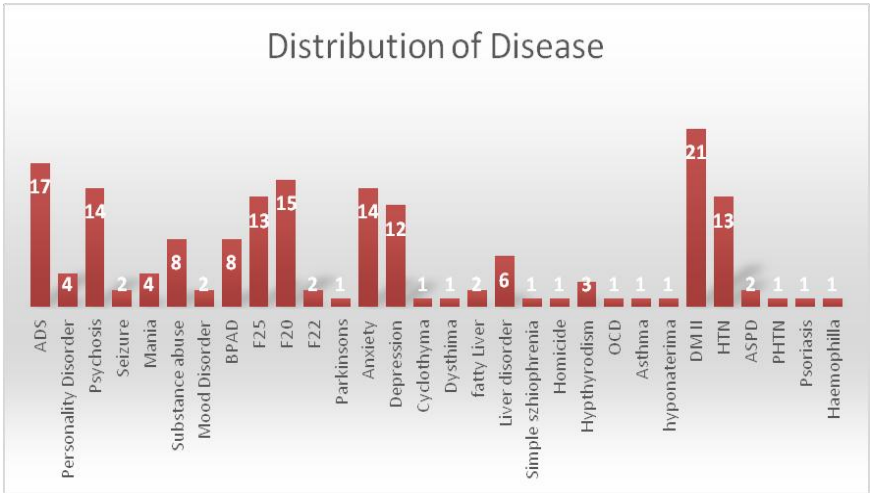

Figure No:1 Distribution of disease.

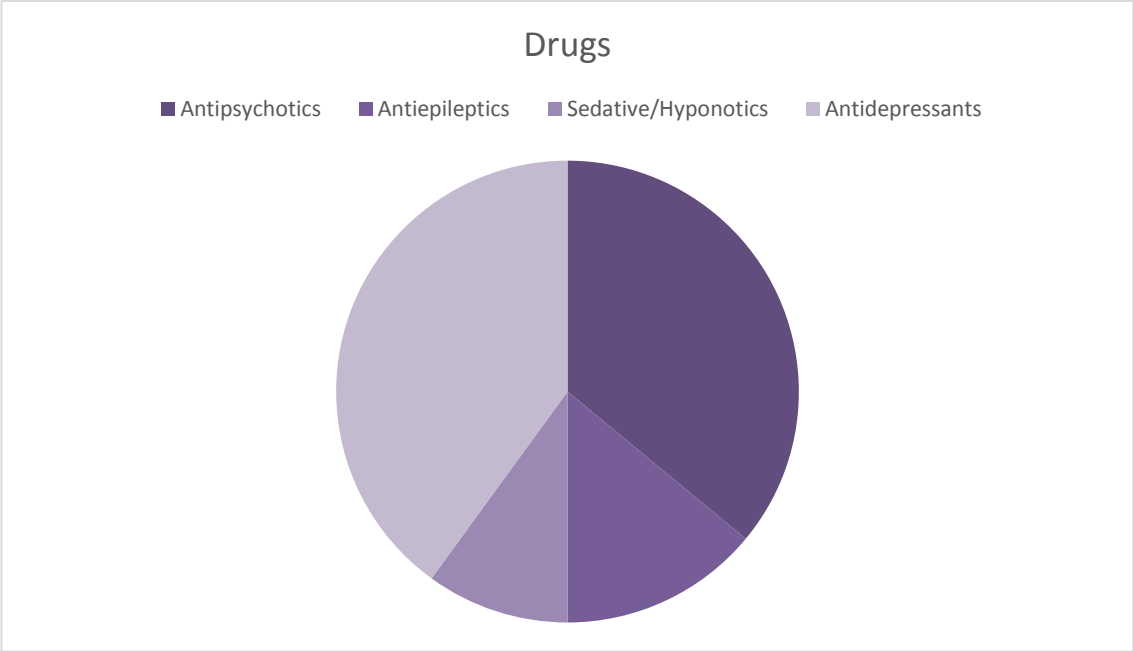

Figure No:2 Drug distribution.

Table No:1 ADR Identified.

ADR	Frequency (%)
EPS	1(1.26%)
Constipation	6(7.6%)
Somnolence	7(8.9%)
Weight gain	5(6.3%)
Akathisia	1(1.26%)
RLS	3(3.8%)
Decreased appetite	3(3.8%)
Increased appetite	5(6.3%)
Dryness of mouth	4(5.06%)
Nausea & vomiting	1(1.26%)
Difficulty in urination	1(1.26%)
Diffuse alopecia	1(1.26%)
Acidity	8(10.12%)
Acne	3(3.8%)
Parkinson's Disease	2(2.53%)
Anxiety	1(1.26%)
Dizziness	4(5.06%)
Dry eye	2(2.53%)
Gastritis	7(8.9%)
Skin Rash	1(1.26%)
Weakness	2(2.53%)
Sleep Talking	2(2.53%)
Headache	4(5.06%)
Hypersalivation	5(6.3%)
Total	79(100%)

A total of 75(92.6%%) patients reported with ADR. Most common ADR found was acidity, gastritis and somnolence. A total of 79 ADR was identified from the 81 patients during the study period. Causality assessment based on Naranjo scale revealed that 67.08% were probable and 20.25% were definite.

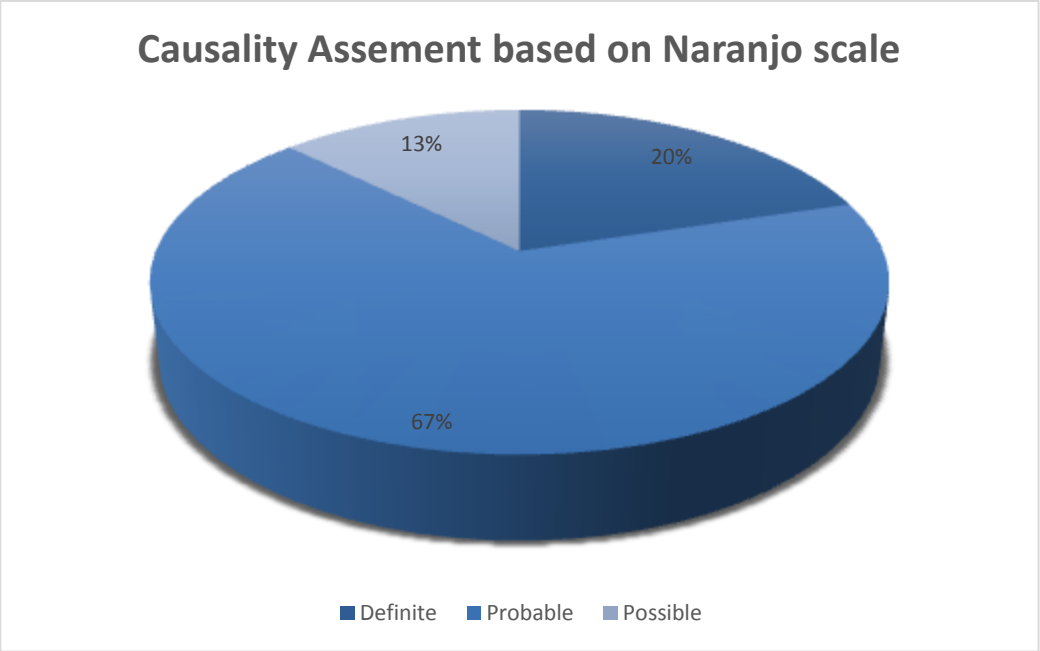

Figure No.3 Naranjo's causality assessment.

The assessment by WHO-UMC scale revealed 24.0% were found to Certain, 45.57% identified as likely/probable, 22.79% were possible and remaining were unlikely.

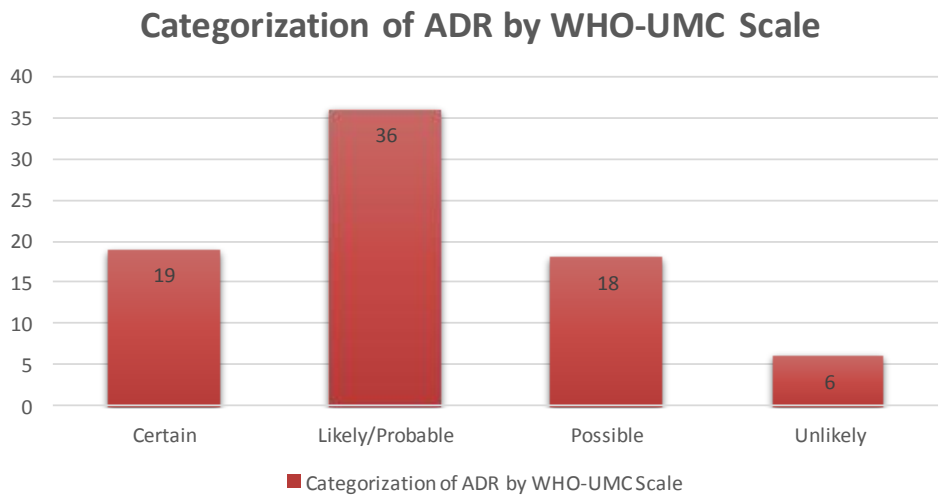

Fig no 4: WHO-UMC Causality Assessment.

On doing severity assessment of ADR by using Modified Hartwig and Seigel scale, 16.45% level 4b, 20.25% were level 4a and 25.31% were level 2 reactions.

Table No: 2 Severity assessment.

Severity		No. of ADR (Percentage)
Mild	level 1	12(15.19%)
	Level 2	20(25.31%)
Moderate	Level 3	11(13.92%)
	Level 4 a	16(20.25%)
	Level 4 b	13(16.45%)
	Level 5	7(8.86%)
Severe	Level 6	0
	Level 7	0

Schumock and Thronton scale were used to classify the preventability showed that majority were preventable while only were non preventable ADRs. (Fig no. 3).

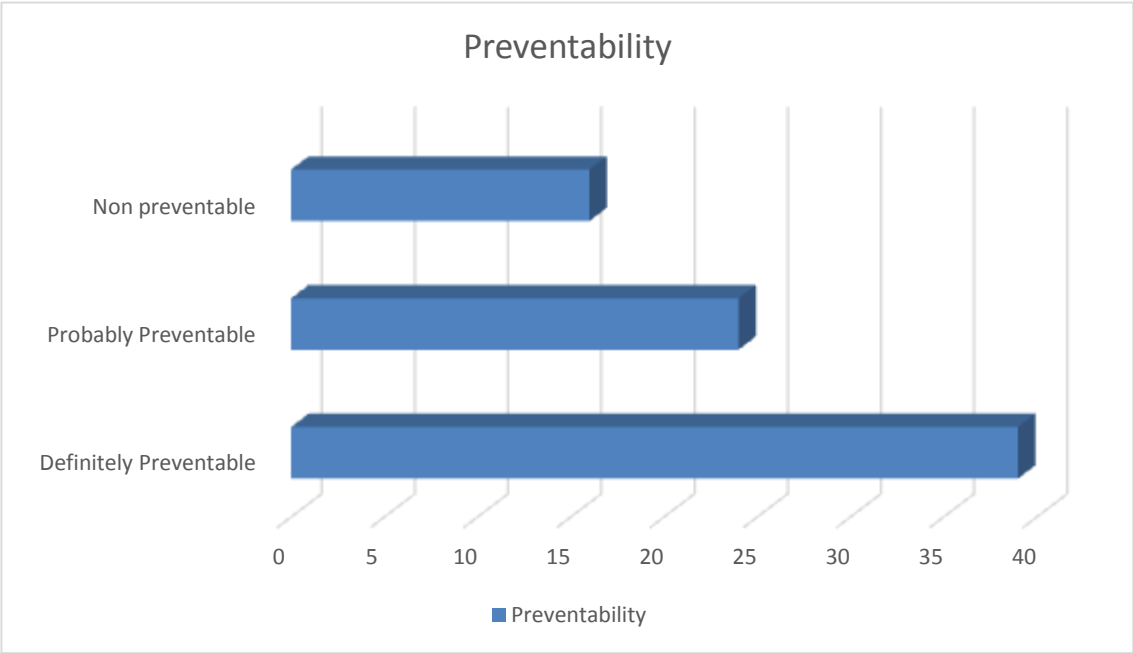

Fig no: 5 Preventability assessment.

DISCUSSION

Analysis of the obtained data shows that both psychiatric and non- psychiatric medications were associated with ADRs. Antidepressants (40%) followed by antipsychotics (36%), antiepileptics (14%) and sedative-hypnotics (10%) caused ADR in the present study, while study done by Thomas et al; and Szabo et al; showed that non-psychiatric medication were more frequently caused ADR than psychiatric drugs [9,10]. In the current study, acidity, gastritis and somnolence were the most common reported ADRs whereas in study conducted by Viswanathan et al; parkinsonism, tachycardia and tremor were the most common ADR caused by psychiatric drugs [11]. Another study by R Abou et al; reported weight gain, pseudo-parkinsonism and constipation as the most common ADRs [12].

Causality assessment based on Naranjo scale revealed that most of the ADRs were probable, followed by definite. This finding was in accordance with four other studies in which most of the ADRs were probable in nature [11-15]. The assessment by WHO-UMC scale revealed that majority of them were identified as likely/probable (45.5%), followed by certain (24%), possible (22.7%) and remaining were unlikely, and this was similar to the study by Sengupta et al; were majority of ADRs belonged to probable type and contrast with the findings of study conducted by R Abou et al; most of them were possible [12,15].

As per modified Hartwig & Seigel scale for severity assessment most of the ADRs were moderate followed by mild and severe. This was in accordance with study conducted by Sankhiet et al; [15]. In contrast to our findings, other studies reported the majority of ADRs were mild and moderate in severity [12]. Schumock and Thornton scale revealed that majority of the suspected ADRs were of the definitely preventable type followed by probably- preventable and non-preventable and this was differed from other studies were probably preventable accounted the for the majority of the reported ADRs [15].

CONCLUSION

The study offers a representative profile of the ADRs which can be expected in the psychiatry inpatients. The study revealed most of the ADR were probable by Naranjo scale. Majority of the ADRs reported during the study were mild and moderate in nature. The ADR can affect the medication adherence and treatment outcome of patient. As almost half of the identified ADRs were definitely preventable, there are clearer indications for areas where efforts for improvement of patient safety could be intensified. Similar studies conducted at regular intervals can help to assess the changing pattern of ADR as well as the identification of newer ones.

ABBREVIATIONS

ADRs : Adverse drug reactions,
WHO-UMC : World health organisation Uppsala monitoring centre

SUPPLEMENTARY MATERIALS: Nil

AUTHOR CONTRIBUTIONS:
All authors contributed equally to the study and article.

CONFLICT OF INTERESTS:
There is no conflict of interest for any one of the authors.

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