

Research Article**PREVENTABILITY ASSESSMENT OF ADVERSE DRUG REACTIONS IN PSYCHIATRY INPATIENT DEPARTMENT USING MODIFIED SCHUMOCK AND THORNTON'S SCALE**Nooja Moinudeen ¹, Thazneem Bagum T.D ¹, Dr. Manoj K ^{2*}, Dr. Alfet Raju ³, Dr. L. Panayappan ⁴, Dr. K.Krishnakumar ⁵¹ Pharm D students, Department of Pharmacy Practice, St. James College of Pharmaceutical Sciences, KUHS University, Chalakudy-680307, Kerala, INDIA.^{2*} M.B.B.S., M.D (psychiatry), St. James Hospital, Chalakudy- 680307, Kerala, INDIA.³ Doctor of Pharmacy, Assistant Professor, Department of Pharmacy Practice, St. James College of Pharmaceutical Sciences, KUHS University, Chalakudy- 680307, Kerala, INDIA.⁴ M.Pharm, PhD, Head of the Department, Department of Pharmacy Practice, St. James College of Pharmaceutical Sciences, KUHS University, Chalakudy- 680307, Kerala, INDIA.⁵ B.Sc, M.Pharm, Ph.D, Principal, St. James College of Pharmaceutical Sciences, KUHS University, Chalakudy-680307, Kerala, INDIA.

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ABSTRACT

Aim: To assess the preventability of Adverse Drug Reactions in a psychiatry inpatient department using Modified Schumock and Thornton's scale.

Objectives: To monitor and report the nature of Adverse Drug Reactions in psychiatry inpatient department. To assess the preventability of documented Adverse Drug Reactions using Modified Schumock and Thornton's scale.

Method: A prospective observational study was carried out in a psychiatry inpatient department of a 450 bedded tertiary care teaching hospital for a period of six months. Patients of all age groups and both genders with any psychiatric disorder and receiving anti-psychotic medications were included in the study. Patients who were suffering from malignancies, terminally ill and mentally retarded were excluded from the study. Inpatients with Adverse Drug Reactions were screened and documented in standard data entry form. The preventability assessment of documented Adverse Drug Reactions was done using Modified Schumock and Thornton's Scale.

Results: A total of 37 Adverse Drug Reactions were documented from which Constipation 21.62% (n=8) followed by Akathisia 10.81% (n=4) was the most commonly reported Adverse Drug Reaction. Olanzapine 18.91 % (n=7) followed by Risperidone 16.21% (n= 6) were associated with maximum number of Adverse Drug Reactions.

Conclusion: The following study revealed that majority of the Adverse Drug Reactions reported was not preventable type using Modified Schumock and Thornton's Scale.

KEYWORDS: Adverse Drug Reaction, Psychiatry inpatients, Anti-psychotic medications, Modified Schumock and Thornton's Scale.

INTRODUCTION

Anti-psychiatrics are a class of medications used to treat a wide range of mental disorders. These drugs decrease the intensity of psychiatric symptoms such as delusions, hallucinations and depression thereby enhancing the mental well-being of psychiatric patients. The association of psychotropic medications with Adverse Drug Reactions is common and can occur even at normal doses used in the

management of psychiatric disorders. These Adverse Drug Reactions can impair quality of life, may lead to poor adherence to medications, cause physical morbidity, issue stigma, and in extreme cases, can be fatal.

Adverse drug reactions (ADRs) are known to be the significant cause of morbidity and mortality both in inpatient and outpatient settings. The common adverse effect of anti-psychiatric medications includes weight gain, tremors, sedation and constipation. Adverse Drug Reaction monitoring in a hospital setting is an important process to identify the patients who are at high risk for developing Adverse Drug Reactions and understand the nature and incidence of Adverse Drug Reactions in a local population. Thus, Adverse Drug Reaction monitoring helps in developing appropriate interventional strategies to manage, prevent and minimize the risk of developing Adverse Drug Reactions and thereby reducing the cost of care.

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A clear understanding of the adverse effects associated with anti-psychiatric therapy could ultimately yield better therapeutic outcomes and increase patient adherence to medications. This study was designed to analyze the drug use pattern of anti-psychiatric drugs and the common adverse effects evoked by them. The aim of this study was to monitor and report the nature of Adverse Drug Reactions in psychiatry inpatient department and to assess the preventability of documented Adverse Drug Reactions using Modified Schumock and Thornton's scale.

MATERIALS AND METHODS

The study was conducted in a multispecialty tertiary care hospital, in the psychiatry department at St. James Hospital, Chalakudy. A total of 120 patients were enrolled in the study in which 34 patients had adverse drug reactions. The study was designed to be a prospective observational study, carried out in

single centre for a period of 6 months (December 2016- May 2017). The sample population was selected by inclusion-exclusion criteria. Patients admitted in the psychiatry department irrespective of age and sex, with any psychiatric disorder and receiving anti-psychotic medications were included in the study. Patients who were suffering from malignancies, terminally ill and mentally retarded were excluded from the study.

Patients who got admitted to psychiatry department were screened for adverse drug reactions and documented in standard data entry form. It included patient demographics, past medication history, lab investigation reports, diagnosis, drugs prescribed and existing co morbidities. The preventability assessment of documented Adverse Drug Reactions was done using Modified Schumock and Thornton's Scale.

RESULT AND DISCUSSION

Table No. 1: Distribution based on age

Age (years)	Frequency (n=34)	Percentage (%)
<18	1	2.94
18-28	5	14.7
29-39	15	44.11
40-49	3	8.82
50-59	6	17.64
>60	4	11.76

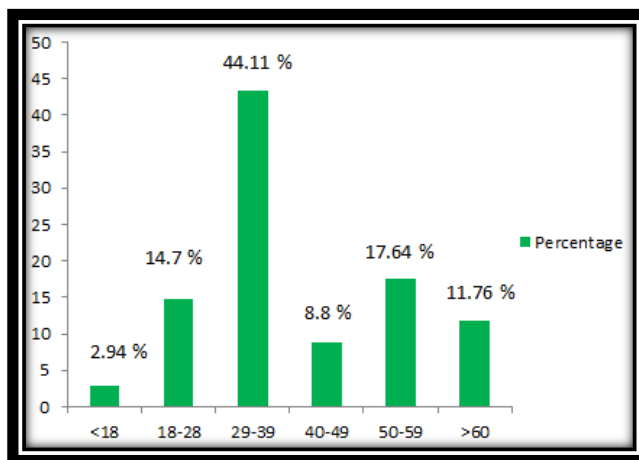


Fig. 1: Percentage distribution based on age

The figure 1 shows percentage distribution based on age:

The respondents were grouped according to their age. Majority of patients belonged to the age group 29-39 (n=15) category with 44.11% followed by 17.64% of the patients belonging to the age group 50-59 (n=6). 14.7%, 11.76% and 8.8% belonged to the age group 18-28 (n=5), greater than 60 years (n=4) and 40-49 (n=3) respectively. Only one patients was in the age group less than 18 years (n=1) with 2.94% (Fig. 1).

The figure 2 shows the percentage distribution of the study population based on gender:

Individuals with Adverse Drug Reactions (n=34) were grouped according to their gender for analysis. The majority of the people of the study population were male, i.e. 65%

remaining 35% were female populations as shown above (Fig. 2).

The graph represents percentage distribution of prescribed number of drugs:

Out of 34 patients with ADR 50% (n=17) were prescribed with 3-4 drugs followed by 44.11% (n=15) with more than 5 drugs and 5.58% (n=2) with 1-2 drugs at a time (Fig. 3).

A doughnut representing distribution of patients based on number of ADR per patient:

Among 34 patients, one suspected ADR was found in 91 % (n=31) and remaining 9 % (n=3) patients experienced at least two ADRs (Fig. 4).

Table No. 2: Distribution based on gender

Study Population	Frequency (n=34)	Percentage (%)
Male	22	64.7
Female	12	35.29

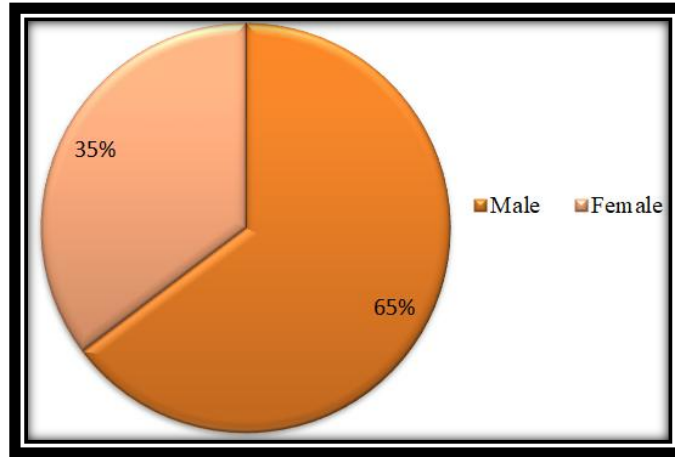


Fig. 2: Percentage distribution based on gender

Table No. 3: Distribution based on prescribed number of drugs

Prescribed no: of Drugs	Frequency(n=34)	Percentage (%)
1-2	2	5.58
3-4	17	50
>5	15	44.11

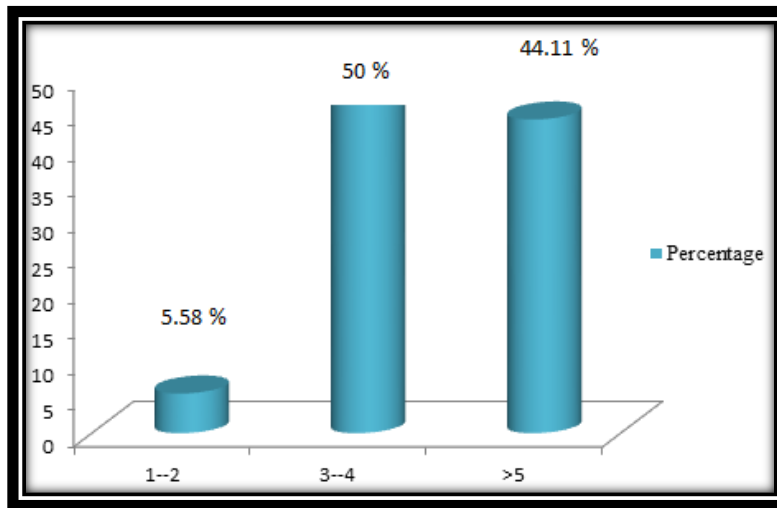


Fig. 3: Percentage distribution based on prescribed number of drugs

Table No. 4: Distribution based on number of ADR per patient (n= 34)

Number of ADR	Frequency (n=34)	Percentage (%)
1	31	91.17
2	3	8.82

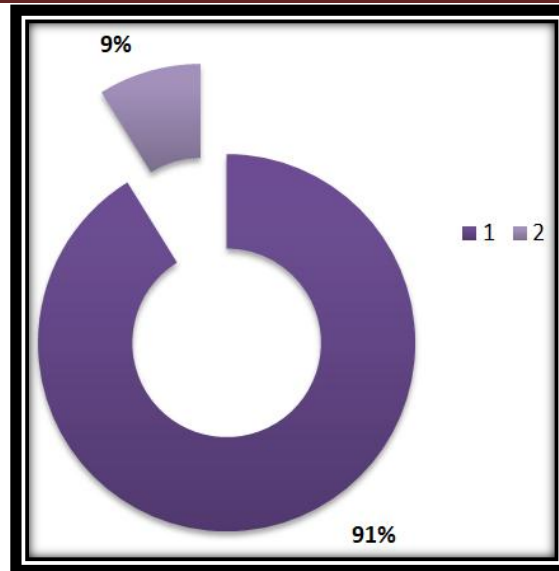


Fig. 4: Percentage distribution based on number of ADR per patient

Table No. 5: Spectrum of different adverse drug reactions and drugs implicated

Type of ADRs	Frequency (n=37)	Percentage (%)	Drugs Implicated
Constipation	8	21.62	Venlafaxine(3), Olanzapine(4) Risperidone(1)
Amenorrhea	2	5.4	Risperidone(1), Valproic acid(1)
Tremor	1	2.7	Venlafaxine(1)
Sedation	2	5.4	Quetiapine(1), Olanzapine(1)
Irritability	1	2.7	Aripiprazole(1)
Postural Hypotension	1	2.7	Risperidone(1)
Hypercholesterolemia	1	2.7	Desvenlafaxine(1)
Erectile dysfunction	2	5.4	Escitalopram(2)
Akathisia	4	10.81	Amisulpride(1), Fluphenazine(1) Lorazepam(1), Clonazepam(1)
Headache	2	5.4	Tofisopam(1), Risperidone(1)
Insomnia	1	2.7	Escitalopram(1)
Weight gain	3	8.1	Risperidone(1), Clozapine(1) Olanzapine(1)
Galactorrhea	1	2.7	Risperidone(1)
Hyperglycemia	1	2.7	Olanzapine(1)
Pedal edema	1	2.7	Sodium valproate(1)
Hypersalivation	3	8.1	Clozapine(3)
Hiccups	1	2.7	Lorazepam(1)
Dry mouth	2	5.4	Quetiapine(2)

The above table describes various adverse drug reactions with the respective causative drugs

Table No. 6: Distribution based on type of ADR

Type of ADR	Frequency (n=37)	Percentage (%)
Constipation	8	21.62
Amenorrhea	2	5.4
Tremor	1	2.7
Sedation	2	5.4
Irritability	1	2.7
Postural Hypotension	1	2.7
Hypercholesterolemia	1	2.7
Erectile dysfunction	2	5.4
Akathisia	4	10.81
Headache	2	5.4
Insomnia	1	2.7

Weight gain	3	8.1
Galactorrhea	1	2.7
Hyperglycemia	1	2.7
Pedal edema	1	2.7
Hypersalivation	3	8.1
Hiccups	1	2.7
Dry mouth	2	5.4

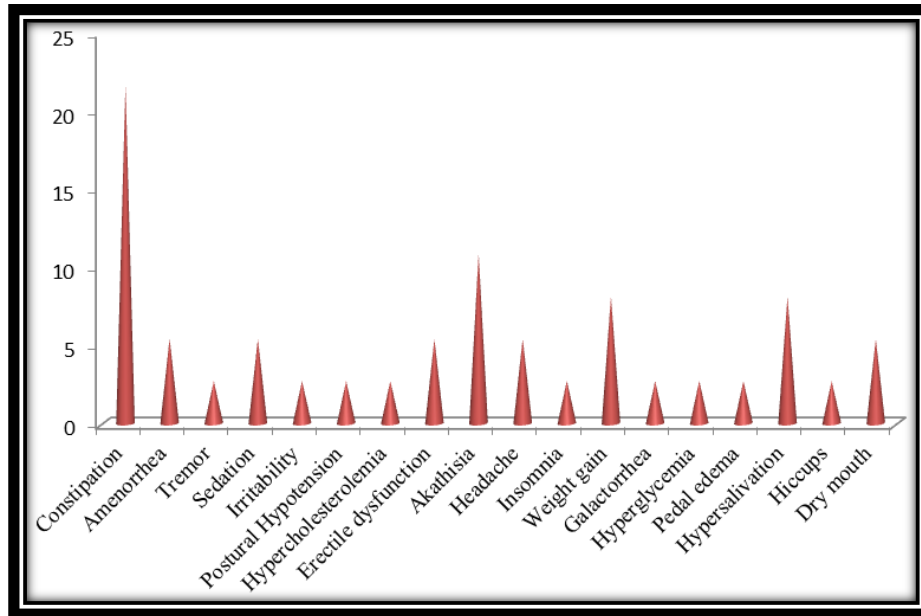


Fig. 5: percentage distribution based on type of ADR

The most common ADR was Constipation (21.62%), followed by Akathisia (10.81%), Weight gain (8.1%) and Hypersalivation (8.1%)

Table No. 7: Distribution based on drugs causing ADRs

Name of Drug	Frequency (n=37)	Percentage (%)
Venlafaxine	4	10.81
Olanzapine	7	18.91
Risperidone	6	16.21
Valproic acid	1	2.7
Quetiapine	3	8.1
Aripiprazole	1	2.7
Lorazepam	2	5.4
Desvenlafaxine	1	2.7
Escitalopram	3	8.1
Amisulpride	1	2.7
Fluphenazine	1	2.7
Clonazepam	1	2.7
Tofisopam	1	2.7
Clozapine	4	10.81
Sodium valproate	1	2.7

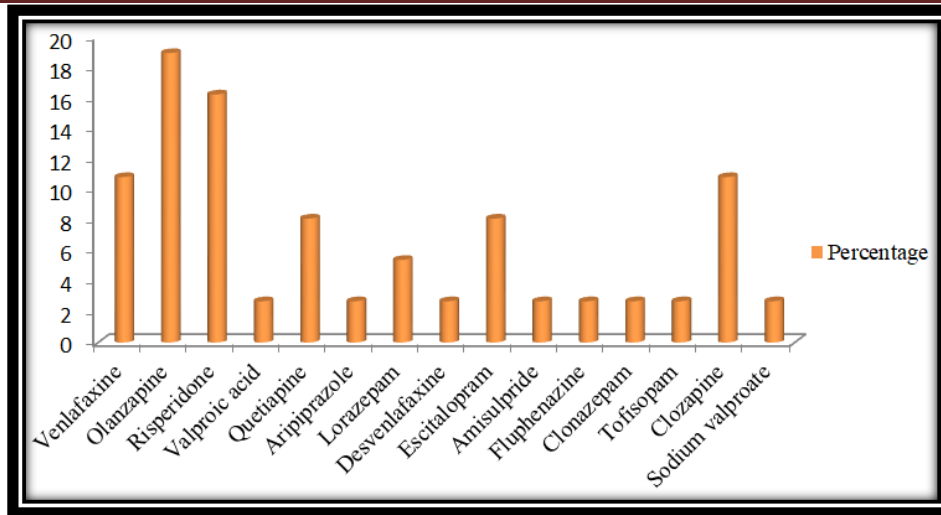


Fig. 6: Percentage distribution of drugs causing ADRs

The figure shows that Olanzapine 18.91% (n=7) was the most commonly implicated drug in ADR followed by Risperidone 16.21% (n= 6), Clozapine 10.81% (n=4) and Venlafaxine (n=4) 10.81% each.

Table No. 8: Distribution based on diagnosis

Diagnosis	Frequency (n=37)	Percentage (%)
Depressive disorder	5	13.51
ADS	8	21.62
Psychosis	8	21.62
EUPD	2	5.4
BPAD	6	16.21
Schizophrenia	4	10.81
Generalized Anxiety Disorder	3	8.1
DSH	1	2.7

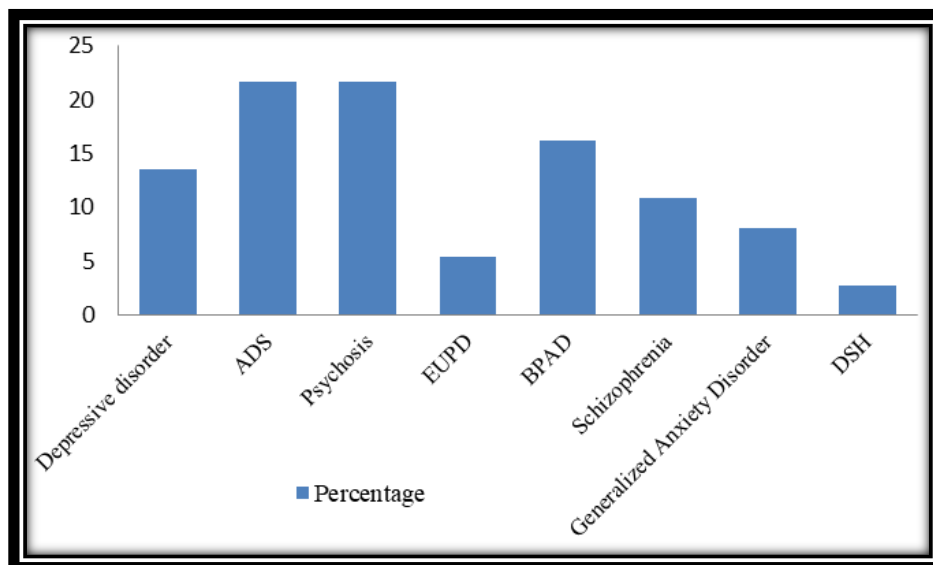


Fig. 7: Percentage distribution based on diagnosis

From the above figure, Alcoholic Dependence Syndrome 21.62% (n=8), along with Psychosis 21.62% (n=8) were the most commonly diagnosed psychiatric condition in patients who developed ADRs followed by BPAD (Bipolar Affective Disorder) 16.21% (n=6) and Depressive disorder 13.51% (n=5).

Table No. 9: Preventability assessment of suspected adverse drug reactions

Assessment	Frequency (n=37)	Percentage (%)
Schumock & Thornton preventability scale		
Not preventable	29	78.37
Probably preventable	7	18.9
Definitely preventable	1	2.7

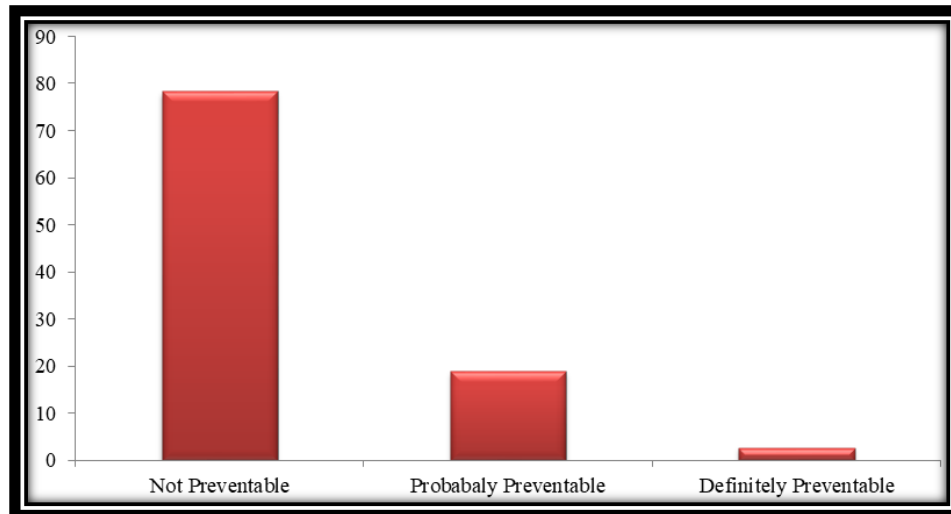


Fig. 8: Percentage distribution based on preventability assessment

Preventability assessment of suspected ADRs was done using Modified Schumock and Thornton scale. Majority of the suspected ADRs 78.37 % (n=29) were of not preventable type followed by probably preventable 18.90% (n=7).

CONCLUSION

The study was performed to determine various adverse drug reactions in patients admitted in the psychiatry department. Majority of the ADRs reported during the study were not preventable type using Modified Schumock and Thornton scale. Constipation was the most common ADR observed. Olanzapine was the drug most commonly associated with different ADRs such as Constipation, Weight gain, Sedation and Insomnia.

Regular intensive monitoring of ADRs in the psychiatry settings might help in early detection of ADRs and reduce the risk caused by ADRs and thereby it may improve the quality of care, reduction in the treatment cost and enhancement of medication adherence pattern among patients. Thorough knowledge of the common adverse effects of anti-psychiatric drugs would decrease their incidence and increase patient adherence and enhance therapeutic outcomes.

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