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Prevalence, Pattern and Monitoring of Adverse Drug Reaction in Tertiary Care Psychiatry Setting- A Hospital Based Study in South Kerala

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Authors' contributions

This work was carried out in collaboration among all authors. Author DD designed the study, performed the statistical analysis, wrote the protocol, and wrote the first draft of the manuscript. Authors SPK and KGR supervised the study. All authors read and approved the final manuscript.

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ABSTRACT

Pharmacovigilance programs usually aim to gather information on the effect of prescribed drugs in the real world rather than in groups of short-lived and carefully selected clinical trial populations. Adverse drug reactions (ADR) associated with psychiatric medications may vary among different populations. As compared with other fields, in Kerala the research related to ADRs and Prescription patterns in psychiatry is scarce. A hospital based cross sectional observational study was undertaken in the Mental Health Centre, Trivandrum. All psychiatric drugs were closely monitor for adverse drug reaction irrespective of their psychiatric diagnosis. CDSCO Suspected adverse drug reaction reporting form was used for the documentation of adverse drug reaction and the causality assessment was done with naranjo scale .The severity of ADR was assessed using Hartwing scale and Preventability assessment using Modified schumock. In this study it was found the highest incident of ADR was reported with risperidone (24%) followed by valproate (20.1%), clozapine (17%) etc. The patient in psychiatry

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cant identify the adverse effect due to the cognitive impairment. So special attention is necessary for psychiatric patient to find out the incidence of adverse drug reaction and provide the proper management to them.

Keywords: ADR; CDSCO; EPS; NMS; ICD; RLS; TD.

1. INTRODUCTION

An individual affected by psychotic illness is usually a burden to both the society as well as their family in terms of non-productivity. The WHO recognized the significance of mental health and defined it as "a state of complete physical, mental and social well-being" [1]. Good mental health ensures increased productivity at work or studies, strong interpersonal relationships, and decreased tendency for substance abuse. The presence of a mental disorder is characterized by sustained or recurring abnormal behavior that results in personal distress or impaired functioning in one or more areas of life [1]. In 1996, Murray and Lopez predicted--based on global disease burden projection models--that by the year 2020, non- communicable diseases such as depression and heart disease would account for seven out of every ten deaths in developing countries. This implied a steep rise of 77%, from 28.1 million per year in 1990 to 49.7 million per year in 2020 [2]. According to the National Health Survey of India (2015-16) conducted by the Institute of Mental Health and Neurosciences, Kerala: the prevalence of common mental morbidity was 11.0%; depressive disorder 2.49%; neurotic and stress-related disorders 5.43%; and mental and behavioural problems due to psychoactive substance use 10.12%. There were also variations in individual disorders concerning gender--substance abuse being more common amongst males and depression being more common amongst females [3]. Anti psychotic drugs offer great benefits in the treatment of various psychiatric illnesses ranging from mood disorders to schizophrenia and many more. However, this class of drugs have also been found to be equally capable of causing a wide range of adverse reactions that impairs patient's quality of life and leads to noncompliance, and some even fatal [4]. The potential long-term androgenic adverse effects associated with anti psychotic poly therapy is a matter of great concern. Therefore, establishing an empirical foundation for the consequences of this practice is extremely essential. ADR refers to a noxious or unintended response to a drug that occurs at doses normally used in man for prophylaxis, diagnosis, treatment of a disease or modification of a physiological function [5]. Edwards and Aronson (2000) further clarify this drug safety terminology by defining an ADR as "an appreciably harmful or unpleasant reaction which predicts hazard from future administration". Adverse Reactions are further classified into augmented, bizarre, continuous, delayed, end of use and failure of treatment [6,7]. The conventional antipsychotics were associated with extrapyramidal side effects like akathisia, dystonia, parkinsonism and tardive dystonia; which newer second-generation antipsychotics are relatively free from. Some of the atypical anti psychotic agents include clozapine, risperidone, olanzapine, quetiapine, risperidone and amisulpride [7]. Although the newer antipsychotics are associated with a lower risk of extrapyramidal side-effects, these drugs present with their own spectrum of side-effects. Despite the potentially lethal risk of agranulocytosis, clozapine was considered the standard prototype treatment in the early 1960s. It modestly improves negative symptoms exhibited by chronic psychotic illnesses like apathy, and social withdrawal. Clozapine's unique properties are that it is associated with an extremely low risk of EPS and therefore does not require co-administration of an adjunctive anticholinergic to protect from extra pyramidal side effects (EPS) [8]. Pharmacovigilance programs usually aim to gather information on the effect of prescribed drugs in the real world rather than in groups of short-lived and carefully selected clinical trial populations. ADRs associated with psychiatric medications may vary among different populations. As compared with other fields, in Kerala the research related to ADRs and Prescription patterns in psychiatry is scarce. Most of the ADRs documented in formularies are based on western experience. ADR's in different populations can differ, and it is important for all professionals working in the healthcare field to know about the ADRs in individual populations. The gap that exists within psychiatric medication-related ADR research in Indian populations is the primary rationale for conducting this study. The present study aims to profile suspected ADRs and report its incidence in the psychiatry settings of the Indian context.

2. METHODOLOGY

2.1 Study Area

Mental Health Centre, Trivandrum Kerala; it is a tertiary mental health institute under department of health , Government of Kerala with over 500 inpatient bed ,over 4000 inpatients and 40000 outpatients per year.

2.2 Study Population

About 442 patient was recruited based on the inclusion and exclusion criteria

2.3 Study Design

A hospital based prospective,cross- sectional observational study.

2.4 Criteria for Selection Patients

2.4.1 Inclusion criteria

1. Subject who were seeking treatment at Psychiatry IPD for various psychiatric disorders and willing to participate.
2. Patient from all age groups and both sexes were included.
3. Those who understood the purpose of the study and were ready to provide information regarding their health status and those who signed an informed consent documents.

2.4.2 Exclusion criteria

1. Not willing to participate.
2. Having a history of substance abuse,malignancies and terminally ill.
3. Being judged clinically to be at a suicidal risk(too serious to be excluded in the study).
4. Those unable to comprehend for other reasons and mentally retard.

2.5 Sampling Technique

Consecutive sampling was used till the adequate sample size is reached. The first patient was recruited after obtaining ethical committee clearance.

2.6 Study Duration

Starting from January 2019 to July 2020.

2.7 Study Variables

2.7.1 Socio-demographic profile

Including name, age, sex, height, weight, religion, family history, social history, education, occupation, monthly income, final diagnosis, duration of illness, marital status, employment, duration of illness, psychiatric co-morbidity, medical history and medication history.

2.7.2 Psychiatric diagnosis based on ICD 10

The ICD-10 Classification of Mental and Behavioral Disorders, clinical descriptions and diagnostic guidelines.

2.7.3 Psychiatric drug profile

Include brand name, generic name, dose, frequency, duration, start date, stop date, hold date and reason for hold

2.7.4 ADR burden

The term “ADR” is used to describe the noxious or unintended reaction produced by the drug normally used in human. It can be subjective and objective and can be measured. CDSCO Suspected adverse drug reaction reporting form will be used for the documentation of adverse drug reaction and the causality assessment of documented ADR will be done using Naranjo scale .The severity of ADR was assessed using Hartwing scale and Preventability assessment using Modified schumock and Thornton's scale.

3. RESULTS AND DISCUSSION

3.1 Agewise Distribution of Patients

A total of 442 psychiatric patients were recruited for the study based on inclusion and exclusion criteria. Out of this 442 patients, 27.8% were belongs to 31-40 years of age group followed by 41-50 years of age (27.1%), 21-30 years (22.2%), 51-60 years (16.1%), 61-70 years (2.9%), <20 years (2.3%) and .70years (1.6%).(Table1)

3.2 Association of Number of ADR with Age

Amoung the 442 psychiatricpatients, 18% experice no ADRs in their treatment time, 30.31% experience one ADR followed by 26%

experienced two ADRs, 16% experienced three ADRs, 7% experienced 4 ADRs, and 2.26% experienced 5 ADRs during their treatment time. It was found that highest incidence of ADRs was reported in the age group of 41-50 years(28%) and 31-40 years (28%) followed by 21-30 years of age.this result was similar to the study conducted by Nalini R et al.[9] (Table2).

3.3 Gender Wise Distribution of Patients

Among 442 patients studied, in that 59% (n=261) of patients were male and 41% (n=181) were females. In this study majority of psychiatric patients was belongs to male gender. The result was not similar to the study conducted by Siddhartha SB et al in 2016 expressed that a total of 714 patients were monitored, of which 352 (49.2%) were male and 362 (50.7%) were female patients.(Table3)

3.4 Association of Number of ADR with Sex

In association of gender and adverse drug reactions of psychiatric agents, 60% of female experienced ADRs in their treatment time as compared to 40% of male patients.This reveals that adverse drug reactions are highly affected in female gender than males. The result was expressed with the x2 value 5.220 and the p value is not significant in this association. But the study conducted by Nalini et al showed that majority of ADR affected gender belongs to males [9] (Table 4)

Table 1. Age wise distribution of patients

Age in years	Frequency	Percentage
≤ 20	10	2.3
21-30	98	22.2
31-40	123	27.8
41-50	120	27.1
51-60	71	16.1
61-70	13	2.9
> 70	7	1.6

3.5 Association of Number of ADR with Diagnosis

The Table 5 explain the association between adverse drug reaction and disease condition. Out of 442 patients 361 patients experienced the ADRs during their treatment period.Out of this 361 patients, 45% bipolar patients experienced ADR followed by 32% of schizophrenia patients, 5.2% psychosis patients, 10.24% schizo-affective

Table 2. Association of number of ADR with age

Age in years	Number of ADRs						χ2 value	p value
	Number of reactions							
	0	1	2	3	4	5		
≤ 20	3	2	1	2	1	1	27.152	0.615
21-30	17	24	29	15	12	1		
31-40	18	36	29	27	9	4		(Not significant)
41-50	21	44	31	17	6	1		
51-60	17	21	20	8	3	2		
61-70	3	5	2	2	0	1		
> 70	2	2	2	1	0	0		
Total	81	134	114	72	31	10		

Table 3. Genderwise distribution of patients

Sex	Frequency	Percentage
Male	261	59.0
Female	181	41.0

Table 4. Association of number of ADR with sex

Sex	Number of ADRs						χ2 value	p value
	0	1	2	3	4	5		
Male	36	53	46	24	16	6		0.390
Female	45	81	68	48	15	4	5.220	(Not significant)
Total	31	134	114	72	31	10		

Table 5. Association of number of adr with diagnosis

Diagnosis	Number of ADRs						χ2 value	p value
	0	1	2	3	4	5		
Bipolar Mood disorder	30	59	58	27	11	7	33.860	0.111 (Not significant)
Schizophrenia	20	43	34	22	16	2		
Psychosis	4	6	4	8	0	1		
Schizo affective	14	16	10	8	3	0		
Schizophrenia and psychosis	4	6	4	4	0	0		
Others	9	4	4	3	1	0		

patients, 3.87% schizophrenia with psychosis and 3.32% other psychiatric illness patients. In adverse drug reaction disease is not an issue. The reason for adverse drug reaction is only with the use of drugs used for the specific conditions. The total number of adverse drug reaction experienced by 442 samples was 752 and the average number of ADR's per samples was 1.70. A total of 442 patients were screened for the study of whom 134 (30.3%) were suspected of having at least one ADR, 114 (25.8%) having two ADR, 16.3% (72) having three ADR, 2.3% (10) having 5 ADRs and 18.3% (81) having no ADRs in their treatment time.

3.6 Drugs Responsible for 752 Adverse Drug Reactions Noted Among Patients

Among the 442 recruited patients 81.67% (361) experienced 752 adverse drug reactions.

3.7 Spectrum of Suspected Adverse Drug Reactions (ADRS) Noted among 361 Patients

Among the 361 ADR affected patients, majority of patients experience neurological related adverse drug reactions (35.70%) followed by cardiovascular disorders (16.04%), blood related disorders (1.60%), reproductive disorders (2%), urinary disorders (1.2%), GIT disorders (12.33%) ,metabolic disorders (10%), skin related disorders (6%), eye related problems (1%) and general disorders (14.32%). It was found that majority of adverse drug reaction was affected in the nervous system because the drugs used for the treatment of psychiatric disorders produce their action in the central nervous system. Some rare ADRs were noted during the course of study, ie, a rare case of clozapine induced rabbit syndrome (Fig. 2)

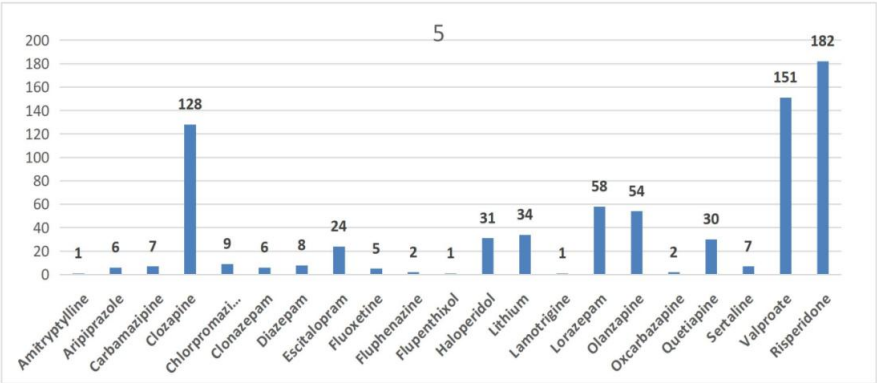

Fig. 1. Concentration of different drugs

In this study it was found that highest incidence of ADR was reported with risperidone (24%) followed by valproate (20.1%), clozapine 128 (17%), lorazepam (7.7), olanzapine (7.1%), lithium (4.2%), haloperidol (4.1%) quetiapine (4%) escitalopram (3.2%), chlorpromazine (1.2%), diazepam (1.1%), carbamazipine and sertaline (0.9%), aripiprazole and clonazepam (0.8%), amisulpride and fluoxetine (0.7%), fluphenazine (0.3%),oxcarbazapine (0.3%) amitryptylline (0.1%) and flupenthixol (o.1%.).but the study conducted by Nalini etal showed tha fluoxetine was the drug that cause majority of ADR(3.89%)f ollowed by sertraline (3.59%), escitalopram (1.28%), imipramine (1.21%). olanzapine (2.90%) followedby haloperidol(1.69%), risperidone(1.25%), chlorpromazine (0.62%), trifluperazine (0.40%), diazepam (1.72%), carbamazepine (0.44%) sodium valproate (0.81%) and lithium(0.59%)[11]

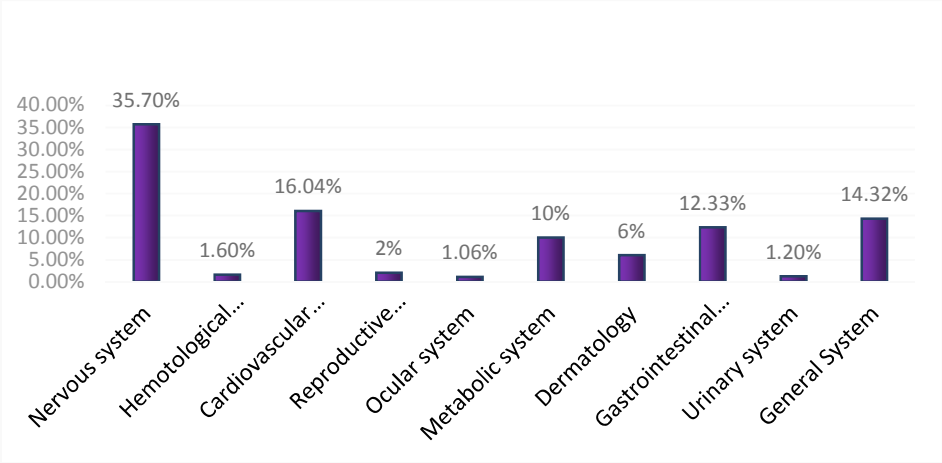

Fig. 2. System associated with adverse drug reactions

3.8 Neurological System Associated with Adverse Drug Reaction to Psychotropic Agents

The neurological system associated adverse drug reactions reported was tremor 11% followed by extrapyramidal symptoms 3.9%, slurring of speech 2.5%,sialorrhea 1.9%, dystonia 2.3%, akathesia 1.6%, somnolence 1.3%, sedation 2.1%, drowsiness 0.8%, headache 0.8%,tardivedyskenesia 0.7%, forgetfulness 0.5%, insomnia 0.4%, heaviness of head 0.3%, dizziness 0.4%, sialorrhea with slurring of speech 0.4%, rabbit syndrom 0.4%, oral EPS with bradykinesia 0.4%, tardive dyskinesia with hand tremor 0.3%,neuroleptic malignant syndrom (NMS) 0.3%, EPS with RLS 0.3%, sialorrhea with difficult in speech 0.3%, TICS 0.3%, catatonia 0.3%, mild weakness in speech 0.1%, bradykinesia 0.1%, tardive dyskinesia with chewing 0.1%, dyskinesia 0.1%, rightside palsy 0.1%, parasthesia on hand 0.1%, ataxia 0.1%, difficulty in speech 0.1%, asterix 0.1%, oromandibular dyskinesia 0.1%, pisa syndom0.1%, oculoglyric crisis 0.1%, dysphonia0.1%, protruding of tongue 0.1%, vertigo 0.1%,rigidity 0.1%, delirium 0.1%, asthesia 0.1% and somnolence with fatigue 0.1%. (Fig. 3)

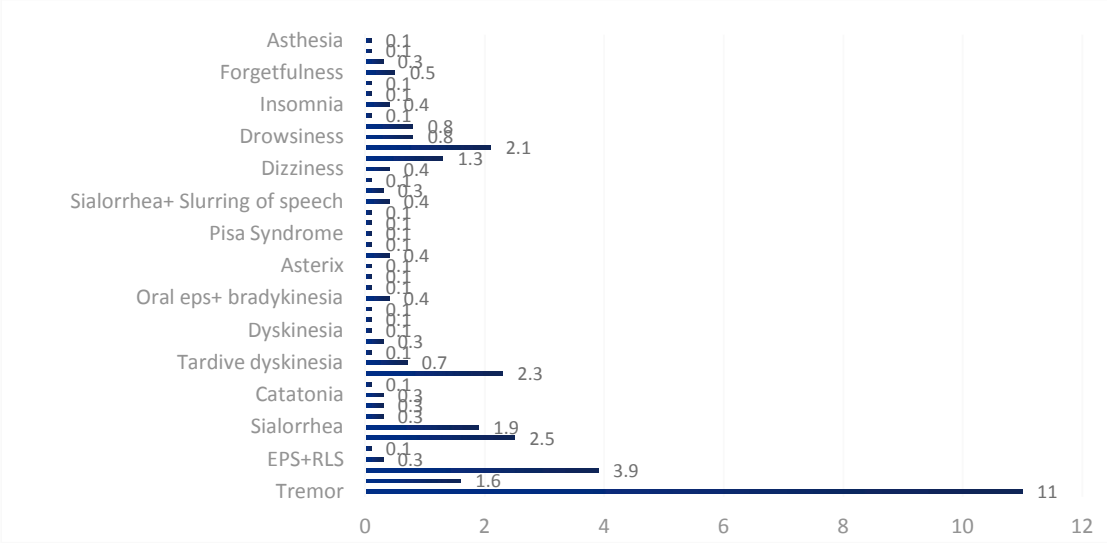

Fig. 3. Neurological system associated with adverse drug reaction to psychotropic agents

3.9 Hemotological System Associated with Adverse Drug Reaction to Psychotropic Agents

Out of 1.6% of total hemotological related ADRs, 1.2% was reported as neutropenia followed by 0.1% folate deficency and0.3% anemia.(Fig. 4).

3.10 Cardiovascular System Associated with Adverse Drug Reaction to Psychotropic Agents

The list of psychotropicdrug induced cardiovascular disorder reported was 6.6% of hypotension followed by tachycardia 2.9%, Twave inversion 2.5%, hypertension 2.5%, ST elevation 0.7%, bradycardia 0.55 and palpitation 0.3%. The total percentage of ADR reported was 16%. (Fig. 5).

3.11 Ocular System Associated with Adverse Drug Reaction to Psychotropic Agents

The eye related ADRs reported was 0.1% of diplopia followed by eyelid oedema 0.1%, eye itching 0.1%, blurring of vision 0.3% and nystagmus 0.4%. (Fig. 6).

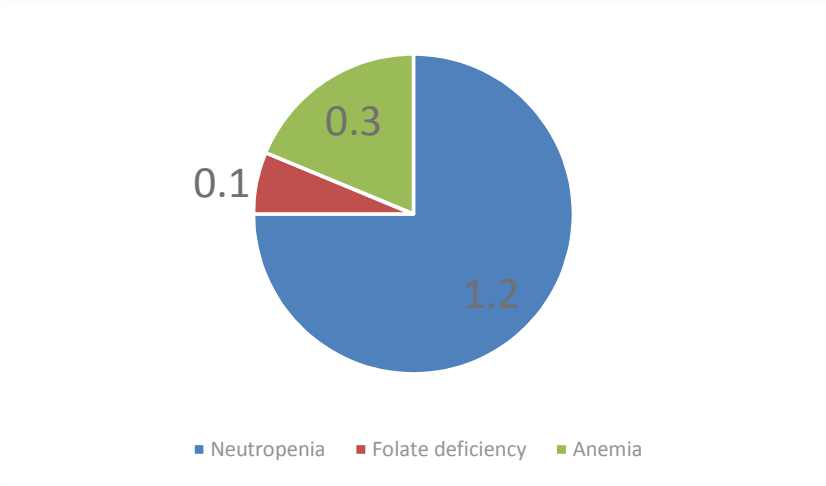

Fig. 4. Hemotological system associated with adverse drug reaction to psychotropic agents

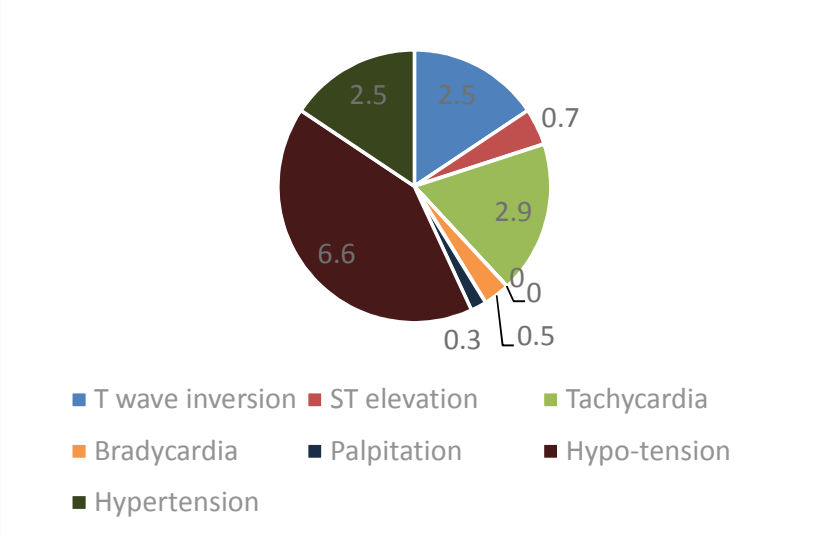

Fig. 5. Cardiovascular system associated with adverse drug reaction to psychotropic agents

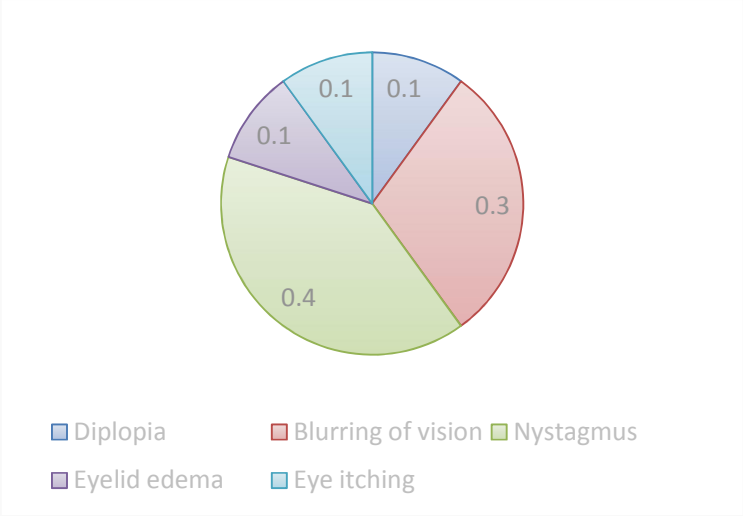

Fig. 6. Ocular system associated with adverse drug reaction to psychotropic agents

3.12 Endocrinal System Associated with Adverse Drug Reaction to Psychotropic Agents

The endocrine related problems reported as ADRs were 4.3% of diabetes mellitus followed by 2.8% hypothyroidism, 1.3% weight gain, dyslipidemia 1.1%, hyperthyroidism 0.3%, weight loss 0.1% and hyperprolactemia 0.1%. (Fig. 7).

3.13 Dermatological System Associated with Adverse Drug Reaction to Psychotropic Agents

The skin related ADRs Reported during study time was 0.9% pruritis followed by 0.8% psoriatic lesions, itching 0.8%, 0.5% skin lesions, 0.4 erythemia, dermatitis 0.4%, cellulitis 0.3, scaling 0.3%, achneform erruption 0.1%, papulovascular eruption 0.1%, exfoliation of hand 0.1%, ezhematous lesion 0.1%, redness of lips 0.1%, sweating 0.1%, lips blistering 0.1%, callosity 0.1%, echymosis 0.1%. (Fig. 8).

3.14 Gastrointestinal System Associated with Adverse Drug Reaction to Psychotropic Agents

The gastrointestinal system associated ADRs reported during the study time was 3.3% liver function elevation followed by 2.8% constipation, 2% gastritis, 0.7%hiccups, 0.5% flatulence, polydipsia 0.4%, tooth abscuss 0.4%, diarrhea 0.3%, glossitis 0.3%, abdominal pain 0.3%, anorexia 0.3%, toothache 0.3%, xerostomia 0.1%, belching 0.1%, lichen plans 0.1%, icterus0.1%, dehydration 0.1%, hepatitis 0.1% and vomiting 0.1%. (Fig. 9)

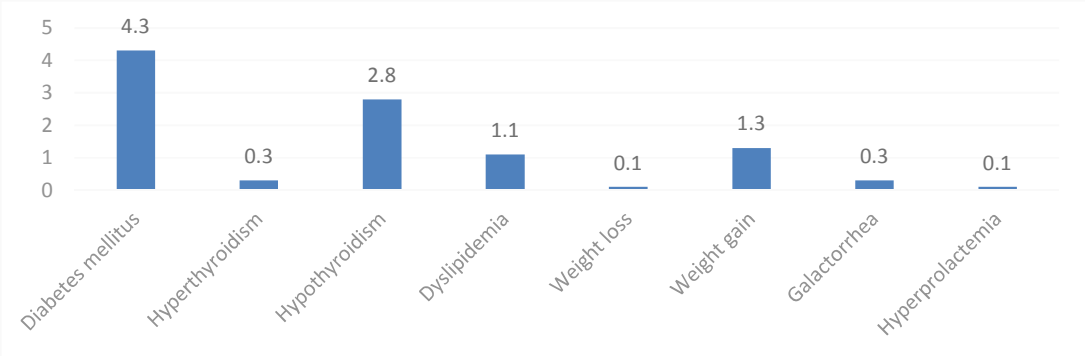

Fig. 7. Endocrinal system associated with adverse drug reaction to psychotropic agents

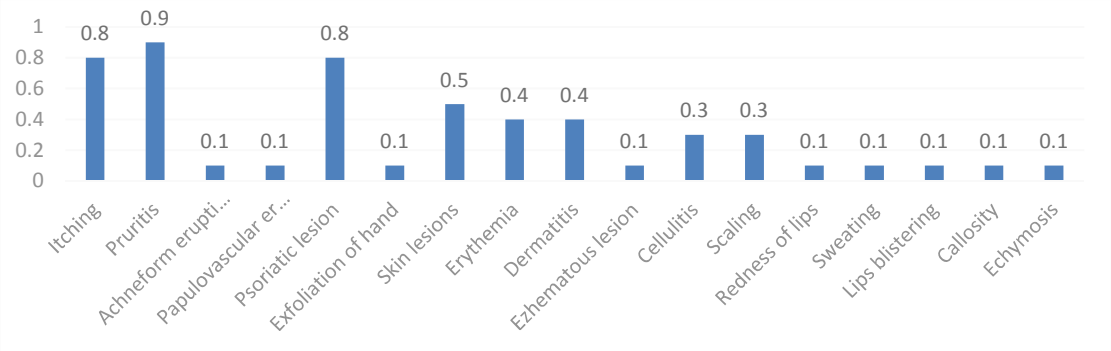

Fig. 8. Dermatological system associated with adverse drug reaction to psychotropic agents

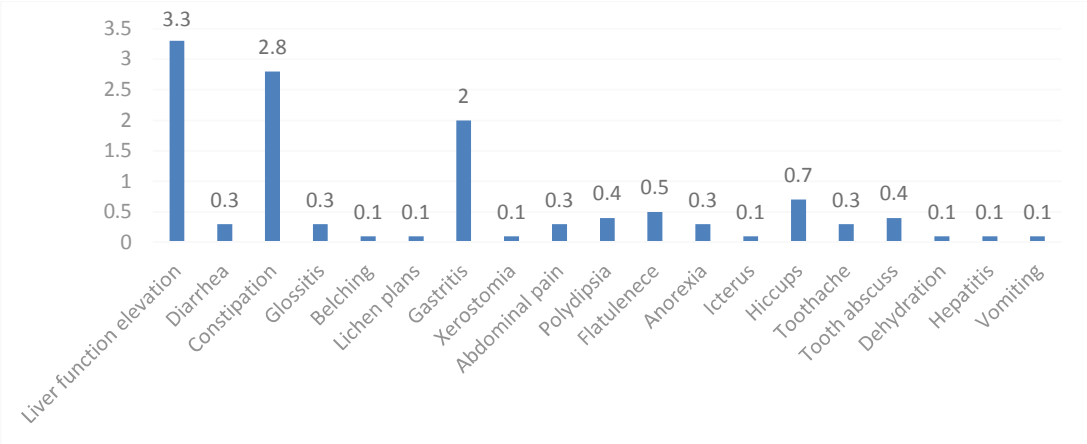

Fig. 9. Gastrointestinal system associated with adverse drug reaction to psychotropic agents

3.15 General System Associated with Adverse Drug Reaction to Psychotropic Agents

The common adverse drug reaction reported was 6.9% fever followed by 2.5% fatigue, 2.1% pedal oedema, 0.8% giddiness, pitting odema 0.4%, otomycosis 0.3%, suicidal ideation 0.3%, cough 0.1%, rhinorrhea 0.1%, 0.1% injection site redness, face oedema 0.1%, rhinitis 0.1%, joint pain 0.1% and leg cramps 0.1%. (Fig. 10).

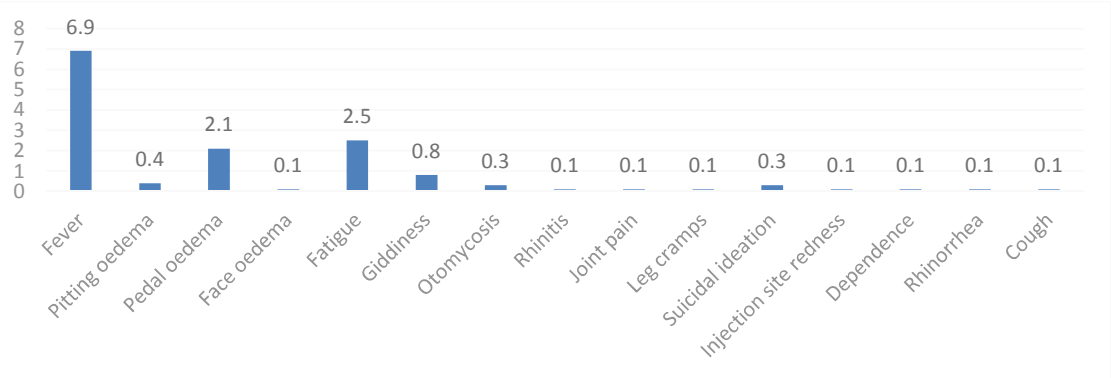

Fig 10. General system associated with adverse drug reaction to psychotropic agents

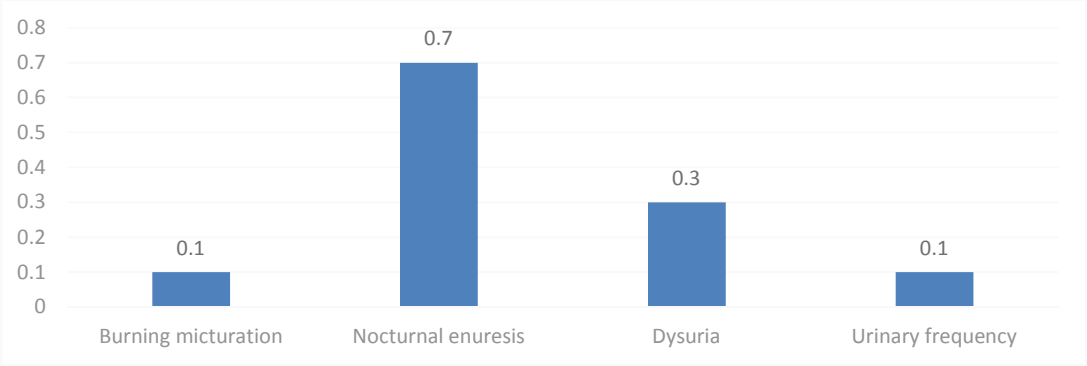

Fig. 11. Urinary system associated with adverse drug reaction to psychotropic agents

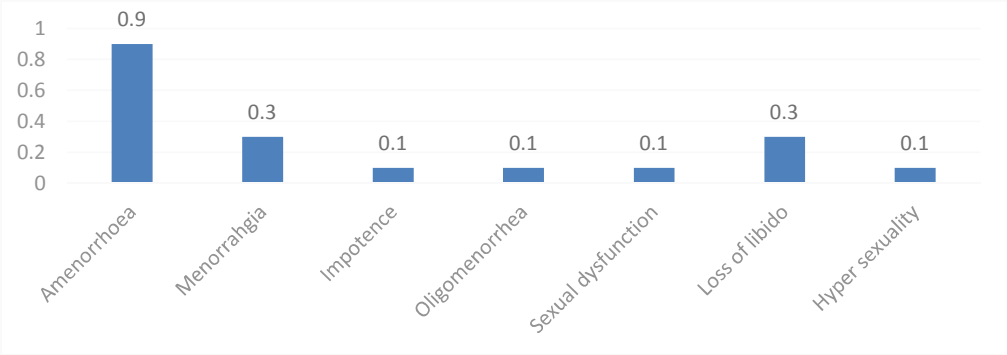

Fig. 12. Reproductive system associated with adverse drug reaction to psychotropic agents

3.16 Urinary System Associated with Adverse Drug Reaction to Psychotropic Agents

The urinary system related ADRs reported was nocturnal eneuresis 0.7% (5) followed by dysuria 0.3% (2), burning micturation 0.1% (1) and urinary frequency 0.1% (1).

3.17 Reproductive System Associated with Adverse Drug Reaction to Psychotropic Agents

The reproductive system associated ADRs reported was 0.9% of amenorrhea followed by 0.3% of menorrhagia, 0.3% loss of libido, 0.1% impotence, 0.1% oligomenorrhea, 0.1% sexual dysfunction and 0.1% hypersexuality (Fig. 12).

3.18 Frequency and Percentage Distribution According to Naranjo Scale

The causality assessment of ADRs induced by psychiatric drug was probable in 79.5% of reactions, possiblein 8.4% of reactions definitive in 12% of reaction and doubtful in 0.1% of reaction. The result was similar to the study done by Nalini et al. [9] showed that most of the ADRs were probable (15.69%) (Table 6)

Table 6. Causality assessment of ADR

Naranjo Scale	Frequency	Percentage
Definitive	90	12.0
Doubtful	1	0.1
Possible	63	8.4
Probable	598	79.5

3.19 Frequency and Percentage of Severity of ADR

The severity of ADRs induced by psychotropic adrugs was L3 moderatein 76% followed by L2 mild in 17%, L6 severe in 5.1%, L1mild 0.7% and L5 severe 0.5%. that means majority of reactions were moderate in type. But thge study conducted by Nalini R et al showed that majority of reactions were found to be mild [9]. (Table 7)

3.20 Frequency and Percentage of Preventability of ADR

It was found that 97.7% of ADRs were definitely preventable type followed by probably preventable 2% and not preventable 0.3%. But the study conducted by Lucca JM showed that the preventability of reported ADRs accounted for 18.7% [10]. (Table 8).

Table 7. Severity of ADRs

Severity	Frequency	Percentage
L1 Mild	5	0.7
L2 Mild	128	17.0
L3 Moderate	572	76.1
L4 Moderate	5	0.7
L5 Severe	4	0.5
L6 Severe	38	5.1

Table 8. preventability status of ADRs

Preventability	Frequency	Percentage
Definitively preventable	735	97.7
Not preventable	2	0.3
Probably preventable	15	2.0

4. CONCLUSION

Like other department the psychiatric drugs also cause adverse drug reaction. But the major problem is, majority of this adverse drug reactions were under reporting. Because in psychiatry the decision maker is only the physician. The patient in psychiatry cant identify the adverse effect due to the cognitive impairment. So special attention is necessary for psychiatric patient to find out the incidence of adverse drug reaction and provide the proper management to them. During the course of study it was found that the highest percentage of healthcare professionals were unaware about pharmacovigilance and ADR, and they shows no interest in reporting of ADRs. Based on the Preventability scale it was found that 97.7% of ADRs were definitively preventable types, so can predict their ADR from their pharmacological actions. So awareness and early detection of ADR will help the consultant and other health care professionals to make appropriate alterations in drug therapy to reduce the symptoms of ADRs[13].It is the responsibility of clinical pharmacist or those who handle drugs in psychiatric setting should educate the healthcare professionals, patients and their bystanders about the benefit of therapy and importance of ADR reporting. The responsible authority in India also create platform for pharmacovigilance education program for healthcare professionals too that will also help to increase the patient care.

CONSENT

As per international standard or university standard, patients' written consent has been collected and preserved by the authors.

ETHICAL APPROVAL

The study was approved by the institutional ethics committee (3166/16/MHC/TVM) and was conducted for 18 months.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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