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A PROSPECTIVE OBSERVATIONAL STUDY ON DRUG UTILIZATION PATTERN AND PHARMACOVIGILANCE OF PATIENTS ATTENDING PSYCHIATRY OPD IN A TERTIARY CARE HOSPITAL

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Abstract

Background: Drug utilization research (DUR) was defined by WHO as "the marketing, distribution, prescription and the use of drugs in a society, with special emphasis on the resulting social, medical and economic implications". (1) The main aim of drug utilization research is to facilitate safe and effective use of drugs and to assess whether drug therapy is rational or not. Since there is no sufficient data on the utilization pattern of drugs on psychiatric disorders in Chidambaram area, the present study was conducted to analyse the drug utilization pattern and monitor the adverse effects of drugs used in various psychiatric disorders in a tertiary care hospital.

Materials and Methods: This is an observational study conducted by Department of Pharmacology in the Department of Psychiatry, Rajah Muthiah Medical College and Hospital (RMMCH) for a period of one year from January 2018 to December 2018, in which a total of 80 prescriptions were analysed.

Results: Out of 80 prescriptions ,52.50% were males and 47.50% were females. Majority of the patients were in the age group of 36 – 45 years (32.50%). Regarding the disease distribution pattern, 51(63.75%) anxiety disorder, 11(13.75%) depressive disorder, 10(12.50%) adjustment disorder, 4 (5%) obsessive compulsive disorder and 4(5%) schizophrenia cases. Most commonly encountered adverse effects were drowsiness and headache.

Conclusion: Prescription pattern of drugs used for various psychiatric illness were rational, and were according to the drug use indicators by WHO/INRUD. Majority of the drugs (69.34%) were prescribed in their generic names. However, there remains room for improvement, especially in increasing generic prescribing and adherence to the essential drug list.

Key words: Drug utilization research, Psychiatric disorders, Pharmacovigilance.

Introduction

Medicines play a crucial role in the health care system. However, to produce the desired effect, they have to be safe, efficacious and should be used rationally. Desired effects of drug therapy may not be achieved because of under use, over use or misuse of drugs. Recently a large number of newer drugs are emerging continuously which have markedly decreased the total duration of hospital stay, mortality and improved the quality of life. [1] However, in this rapidly expanding field of pharmacotherapy, it is necessary to consider the negative consequences of inappropriate drug use like increased morbidity and mortality to excessive medication and adverse drug reactions. The emerging problems of inappropriate drug usage, clearly demonstrates the need for drug utilization research to ensure safe and effective treatment. Psychiatric disorders pose a substantial burden on public health. Of the top ten health conditions contributing to the Disability Adjusted Life Years (DALYs), four are psychiatric disorders [2]. Psychosis is a symptom of mental illnesses characterized by a distorted or non-existent sense of reality. Psychotic disorders have different aetiologies, each of which demands a unique treatment approach. Common psychotic disorders include mood disorders (major depression or mania) with psychotic features, anxiety disorders, substance induced psychosis, dementia and delirium with psychotic features, delusional disorder and schizophrenia. Among the psychiatric disorders, anxiety disorder accounts to the most common condition. Compared to 2005, in 2015, there has been a 14.9% increase in incidence of anxiety disorder as a result of population growth and ageing[3]. During the past two decades, the development of newer drugs like Selective Serotonin Reuptake Inhibitors (SSRIs) and atypical antipsychotics have drastically changed the drug therapy protocols. Pharmacovigilance is the science and activities relating to the deduction, assessment, understanding and prevention of adverse effects or any other possible drug related problems. (WHO collaborating centre for international drug monitoring) [4]. Adverse drug reaction monitoring is a process of continuously monitoring the undesirable effect suspected to be associated with the use of medicinal products. It provides updated drug safety information to health care professionals and other stake holders including WHO ADRs monitoring centres.

Materials and Methods

Study design

Prospective observational study to analyse the drug utilization pattern and their related adverse effects in patients attending Psychiatric OPD.

Study settings: This study was conducted in Psychiatric OPD, Rajah Muthiah Medical college and hospital, a tertiary care teaching hospital, Chidambaram, Tamil Nadu, India.

Study period: This study was conducted during the period of January 2018 to December 2018.

Sample size calculation: Eighty prescriptions were analysed

Inclusion criteria

- Both male and female
- Age group of 15- 55 years attending Psychiatric outpatient department with psychiatric disorder.

Exclusion criteria

- Patients who could not comply with the study such as mental retardation or severe psychiatric illness.
- Patients who are not willing to participate in the study.
- Patients with severe physical illness.

Ethical committee approval

The study protocol and the informed consent form (English and Tamil language) was submitted to the Institutional Human Ethics Committee, Rajah Muthiah Medical College, Annamalai University and approval with reference no - IHEC/0323/2017 was obtained before the commencement of the study.

Procedure

The study was conducted on 80 patients who visited psychiatric OPD, RMMCH during the period of January to December 2018. The participants were explained in detail about the study and they were also assured that their identity would be kept confidential. Informed written consent was obtained from each participant. Illiterate patients gave their left thumb impression in the presence of witness. The patients were followed up after 2 week's interval and any adverse drug reactions that developed were noted down. Patient details like Name, age, gender, Outpatient number, educational status, occupation, income were obtained. Type of illness, type of medications prescribed, dosing schedule and duration were noted. On follow up, adverse reactions if any were noted. The collected data were analysed according to WHO/INRUD drug use indicators, prescribed drugs were classified according to Anatomical Therapeutic Chemical (ATC) classification code and Prescribed daily dose (PDD) and its ratio to defined daily dose (DDD) was calculated.

Statistical analysis

The data was expressed in number and percentage. Descriptive statistical analysis was done. Quantitative data were expressed in percentage and proportions.

Results

Majority of the patients belong to the age group of 36-45 years (32.50%). Among the study participants, 52.50% were males and 47.50% were females. A total of 196 drugs were prescribed. Majority of the study participants were graduates. Out of the 80 prescriptions, 51(63.75%) prescriptions were of the diagnosis of anxiety disorder, 11(13.75%) were of Depressive disorder, 10(12.50%) were of adjustment disorder, 4(5%) were of obsessive-compulsive disorder, 4(5%) were of Schizophrenia. Majority of drugs were prescribed in their generic names (69.34%). The Fixed dose combination (FDC) used were Clonazepam with Escitalopram and Clonazepam with Paroxetine. The PDD/DDD ratio was highest for Escitalopram (0.93) and least for Clonazepam (0.07). A total of 196 drugs were prescribed, 97(49.5%) were anti-anxiety drugs, 66(33.67%) were anti-depressants, 4(2.04%) were anti psychotics, 12(6.12%) were multivitamin tablets, 17(8.67%) were H2 blockers. Among the patients diagnosed with anxiety disorder the most commonly prescribed drug was Clonazepam (82.3%) followed by Escitalopram (68.6%), Propranolol (25.4%). In depressive disorder, majority of the patients were prescribed Escitalopram (81.8%), followed by Clonazepam (72.7%), Lorazepam (27.2%). In schizophrenia, most commonly prescribed drug is Quetiapine and Clonazepam. In obsessive compulsive disorder, Clonazepam and Fluoxetine was prescribed. In adjustment disorder, Clonazepam was prescribed for 70% of patients, Propranolol in 40%, Escitalopram in 40%, Alprazolam in 30% of patients.

Discussion

The present study was undertaken to analyze the drug utilization pattern and pharmacovigilance among patients attending the psychiatry OPD in a tertiary care hospital. The findings have been compared with similar studies conducted in India and elsewhere to contextualize our observations.

Age-wise distribution pattern

In our study, the majority of patients (32.50%) belonged to the age group of 36–45 years. This is comparable to the findings by Trivedi et al. (2013) [(5)] , who reported a higher prevalence of psychiatric illnesses in the age group of 31–40 years. Similarly, Karan et al [(6)] observed that the age group 21–40

years constituted the major portion of psychiatric patients. The clustering of psychiatric morbidity in this productive age group could be attributed to increased psychosocial stress, work-related pressure, and lifestyle factors during this phase of life.

Gender distribution pattern

Our study observed a slight male preponderance (52.50%) compared to females (47.50%). Sethi et al. (2011) [7] also reported a higher prevalence of psychiatric disorders among males (56%) in their study. This male predominance could be due to greater exposure to occupational and financial stress or possibly higher healthcare-seeking behaviour among men.

Socioeconomic status

Using the modified Kuppuswamy scale (2018), the majority of patients (48.75%) in our study belonged to the lower middle class. This aligns with the study by Goyal et al. (2014) [8] who found that psychiatric illnesses were more common among lower and lower-middle socioeconomic groups. Economic hardship may contribute to psychological stress and increase vulnerability to psychiatric disorders. Educational status also plays a role; in our study, most participants had completed at least secondary education or diploma, suggesting a relatively literate study group.

Morbidity distribution pattern

Anxiety disorder (63.75%) was the most common diagnosis in our study, followed by depressive disorder (13.75%) and adjustment disorder (12.50%). This is consistent with Goutam et al. (2014) [9], who reported anxiety and depression as the most prevalent psychiatric conditions in outpatient settings. The higher incidence of anxiety disorders reflects global trends as reported by WHO, where anxiety disorders constitute a significant proportion of mental health morbidity.

Assessment of prescription pattern as per WHO/INRUD drug use indicator

The average number of drugs per prescription in our study was 2.45, which is comparable to the findings by Karan et al [6]. About 21.42% of antipsychotics were from the Tamil Nadu essential drug list, suggesting scope for improvement in adherence to essential medicine lists. The percentage of drugs prescribed by generic name was 69.34%, which is lower than the ideal WHO recommendation (100%) but still appreciable. Similar observations were noted by Mengistu et al (2020) [10] in which 100% of drugs were prescribed from Essential drug list and around 88% of drugs were prescribed in generic names highlighting more compliance with WHO prescribing indicators in psychiatric practice.

ATC/DDD classification of drugs used in psychiatric disorders

Among the drugs prescribed, the PDD/DDD ratio was highest for Escitalopram (0.93) and lowest for Clonazepam (0.07). These findings are in line with the study by Lam et al. (2022)[11]who reported similar dosing patterns with SSRIs being the most prescribed antidepressants, often at doses slightly below the defined daily dose. The predominance of SSRIs and benzodiazepines in our study mirrors current global trends favouring these agents for their safety and efficacy profiles. The low PDD/DDD ratio for Clonazepam reflects cautious prescribing to minimize dependence and adverse effects.

Observed adverse drug reactions

Drowsiness was found to be the most commonly encountered adverse reaction, which was found mostly associated with Clonazepam and Alprazolam. This finding correlates with the previous studies done by Davidson JR et al (12) **.**This was followed by headache, which was encountered in patients taking Benzodiazepines and SSRIs, a finding similar to Harnod et al. [13]

Observed prescription pattern in anxiety disorders

Anxiolytics like Benzodiazepines remain the mainstay of treatment followed by antidepressants. This finding correlates with other studies [14,15]. Among Benzodiazepines, the most common drugs used were Clonazepam followed by Alprazolam, which is similar to the studies done by Dutta et al [16]. This suggests a trend towards the use of short acting Benzodiazepines as it is seen that continuous and prolonged use of long acting Benzodiazepines has resulted in dependence and may have withdrawal symptoms when the dosage of these drugs are reduced or treatment is stopped. [17,18] But this was contrast to a study done by Banerjee et al. [14]

Observed prescription pattern in depressive disorder

The most frequent class of drug prescribed was SSRIs, which is similar to other studies done in Italy [19]**.** Lesser side effects and better tolerability of SSRIs is the reason behind its frequent use. Escitalopram was the most common SSRI prescribed overall followed by Fluoxetine. In a study done by Grover et al [20], Escitalopram was the most commonly used anti-depressant which was similar to our study. Escitalopram and Clonazepam was the most frequent drug combination prescribed.

Observed prescription pattern in adjustment disorder

Benzodiazepines were prescribed to tackle the depression component of adjustment disorder, as anti-depressants usually take 2 weeks to show clinical response. First line of treatment was Benzodiazepines followed by SSRIs.

Observed prescription pattern in schizophrenia

In a study conducted by Dietmar Winkler et al [21] and Victor BS et al ,[22] Clonazepam was the most common benzodiazepine prescribed for schizoaffective disorder, a finding similar to our study. In a study conducted by Buckley et al [23], Quetiapine is the antipsychotic mostly prescribed, which aligns with our study.

Observed prescription pattern in OCD

SSRIs are currently the first-line pharmacological agent. Fluoxetine was the most commonly prescribed SSRI, a finding similar to the studies done by Jenike MA et al [24] and Tollefson GD et al. [25]

Conclusion

Overall, the prescription pattern observed in our study indicates largely rational drug use aligned with contemporary practice and supported by evidence-based guidelines. However, there remains room for improvement, especially in increasing generic prescribing and adherence to the essential drug list.

Conflict of interest: Nil

Funding: Self

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Table-1: Distribution of subjects based on age

DIAGNOSIS	AGE GROUP (YEARS)				TOTAL
	15-25	26-35	36-45	46-55	
Anxiety disorder	11	9	21	10	51
Depressive disorder	3	3	1	4	11
Adjustment disorder	1	5	1	3	10
Obsessive compulsive disorder	2	0	2	0	4
Schizophrenia	0	1	1	2	4
Total	17 (21.25%)	18 (22.50%)	26 (32.50%)	19 (23.75%)	80

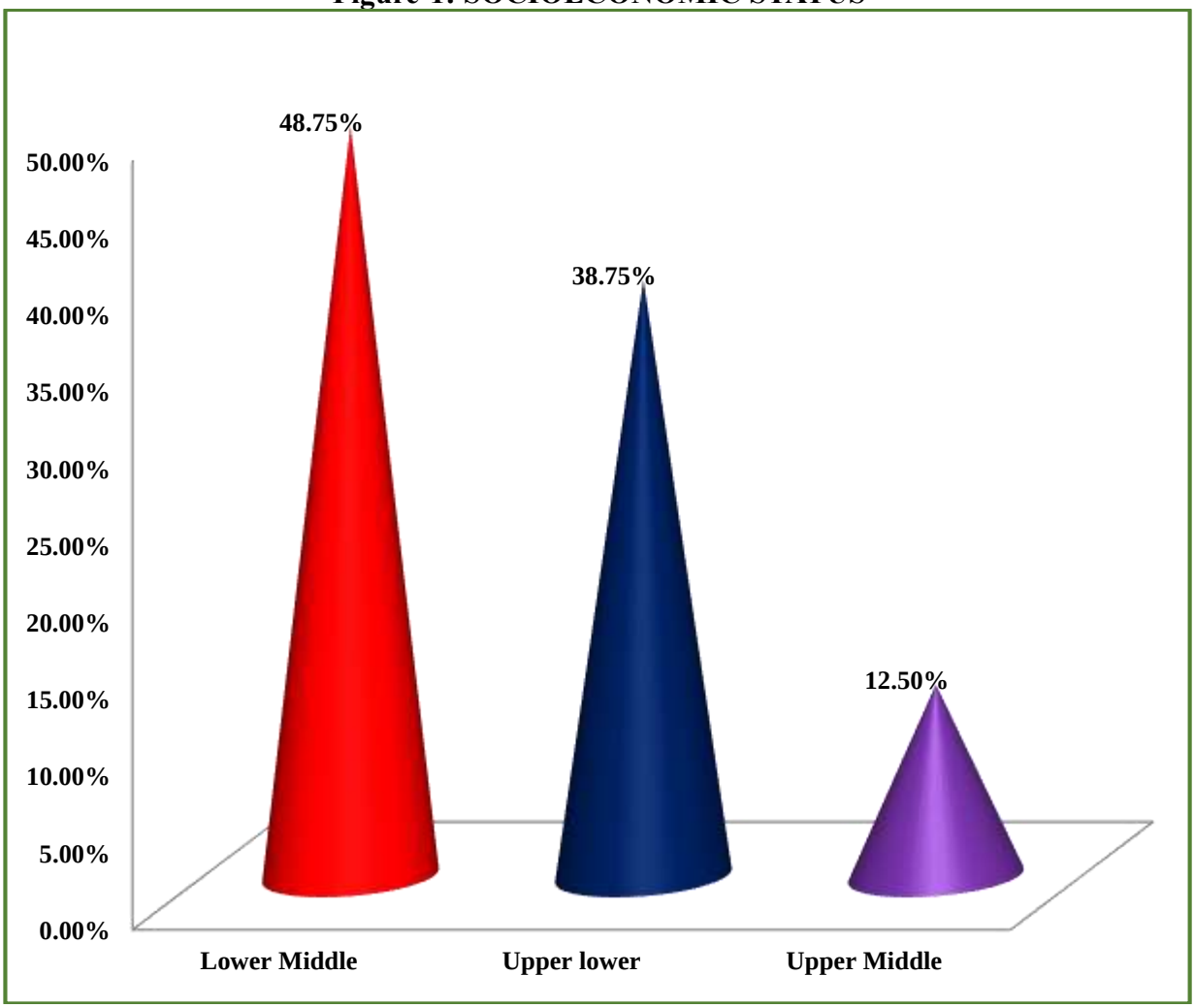
Table-2: Distribution of subjects based on gender

Disorder	Gender		Total
	Male	Female	
Anxiety disorder	27	24	51
Depressive disorder	3	8	11
Adjustment disorder	7	3	10
Obsessive compulsive disorder	2	2	4
Schizophrenia	3	1	4
Total	**42 (52.50%)**	**38 (47.50%)**	**80**

Table-3: Distribution of subjects based on socioeconomic status

Parameter	Group	Number (%)
EDUCATION	1st-5th	6 (7.5%)
	6th-10th	10 (12.5%)
	11th-12th	22 (27.5%)
	Diploma	23 (28.7%)
	Degree	19 (23.8%)
POFESSION	Coolie	7 (8.75%)
	Housewife	24 (30%)
	Student	9 (11.25%)
	Mechanic	7 (8.75%)
	Sales worker	15 (18.75%)
	Farmer	5 (6.25%)
	Business	3 (3.75%)
	Teacher	1 (1.25%)
	Clerk	7 (8.75%)
	Nurse/ lab technician	2 (2.5%)

Figure-1: SOCIOECONOMIC STATUS



According to modified Kuppusamy scale (January 2018), majority of patients 39(48.75%) belong to lower middle class.

FIGURE 2: MORBIDITY DISTRIBUTION PATTERN

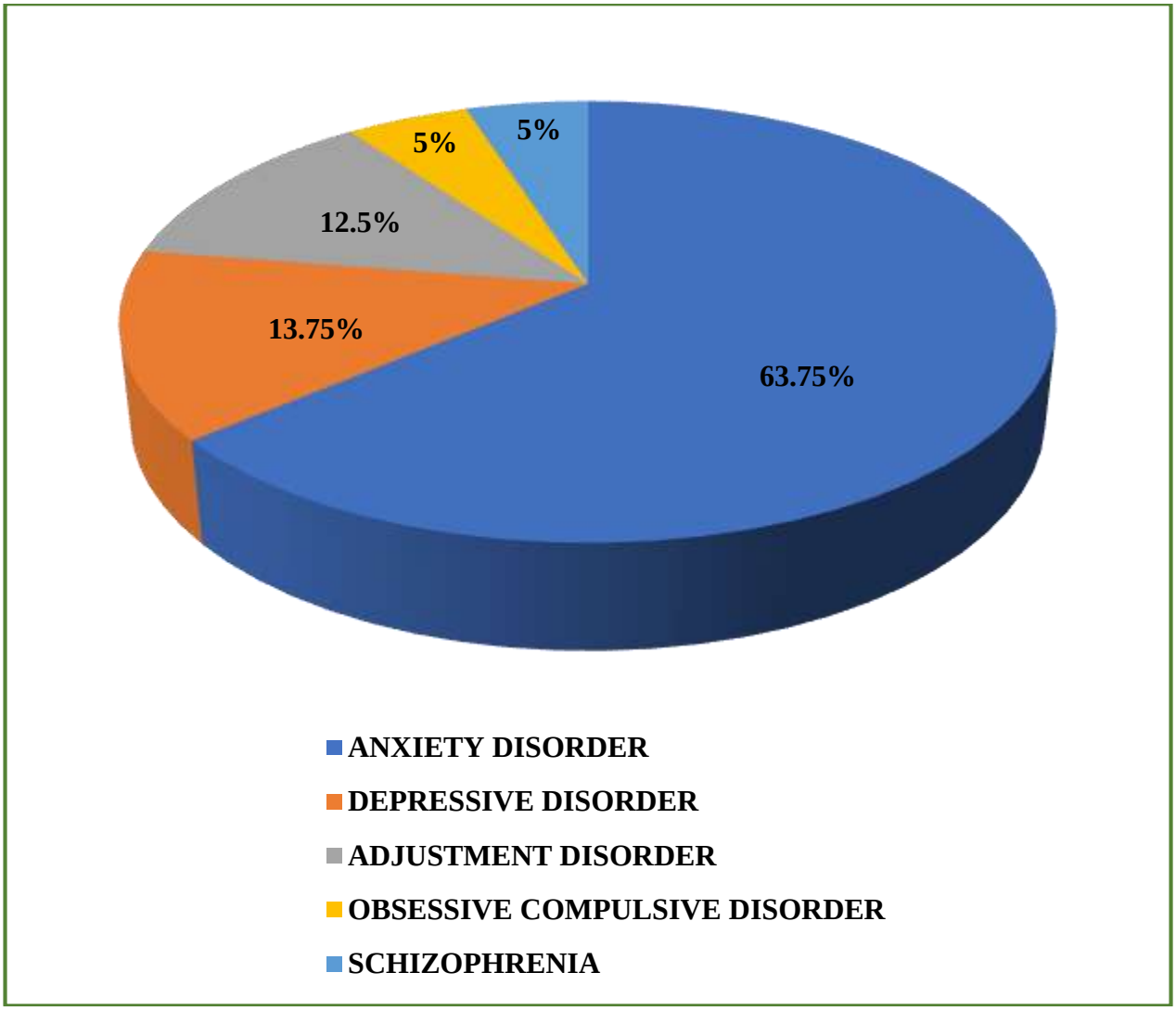


Table-4: Distribution of subjects based on morbidity

DIAGNOSIS	Total number	Percentage (%)
Anxiety disorder	51	63.75
Depressive disorder	11	13.75
Adjustment disorder	10	12.50
OCD	4	5.00
Schizophrenia	4	5.00

Table-5: Assessment of prescription pattern as per WHO/INRUD drug use indicators:

S.No	Drug use indicators	Result
1.	**Average number of drugs per prescription**	**2.45%**
2.	**Percentage of drugs prescribed by generic names**	**69.34%**
3.	**Percentage of prescriptions containing FDC**	**31.25%**
4.	**Percentage of anti-psychotic drugs prescribed from the Tamilnadu essential drug list**	**21.42%**
5.	**Percentage of anti-psychotic drugs dispensed from hospital drug store at free of cost**	**68.87%**
6.	**Percentage of anti-psychotic drugs purchased by patients at cost**	**31.13%**

Table 6: ATC/DDD Classification of drugs used in psychiatric disorder:

DRUG	ATC	PDD	DDD	PDD/DDD
Escitalopram	**N06AB10**	9.375	10	0.9375
Fluoxetine	**N06AB03**	17.5	20	0.875
Lorazepam	**N05BA06**	2	2.5	0.8
Paroxetine	**N06AB05**	12.5	20	0.625
Quetiapine	**N05AH04**	25	40	0.625
Sertraline	**N06AB06**	25	50	0.5
Diazepam	**N05BA01**	4.37	10	0.437
Alprazolam	**N05BA12**	0.32	1	0.32
Propranolol	**C07AA05**	28.23	160	0.176
Clonazepam	**N03AE01**	0.58	8	0.07

Figure-3: Distribution pattern of drugs prescribed

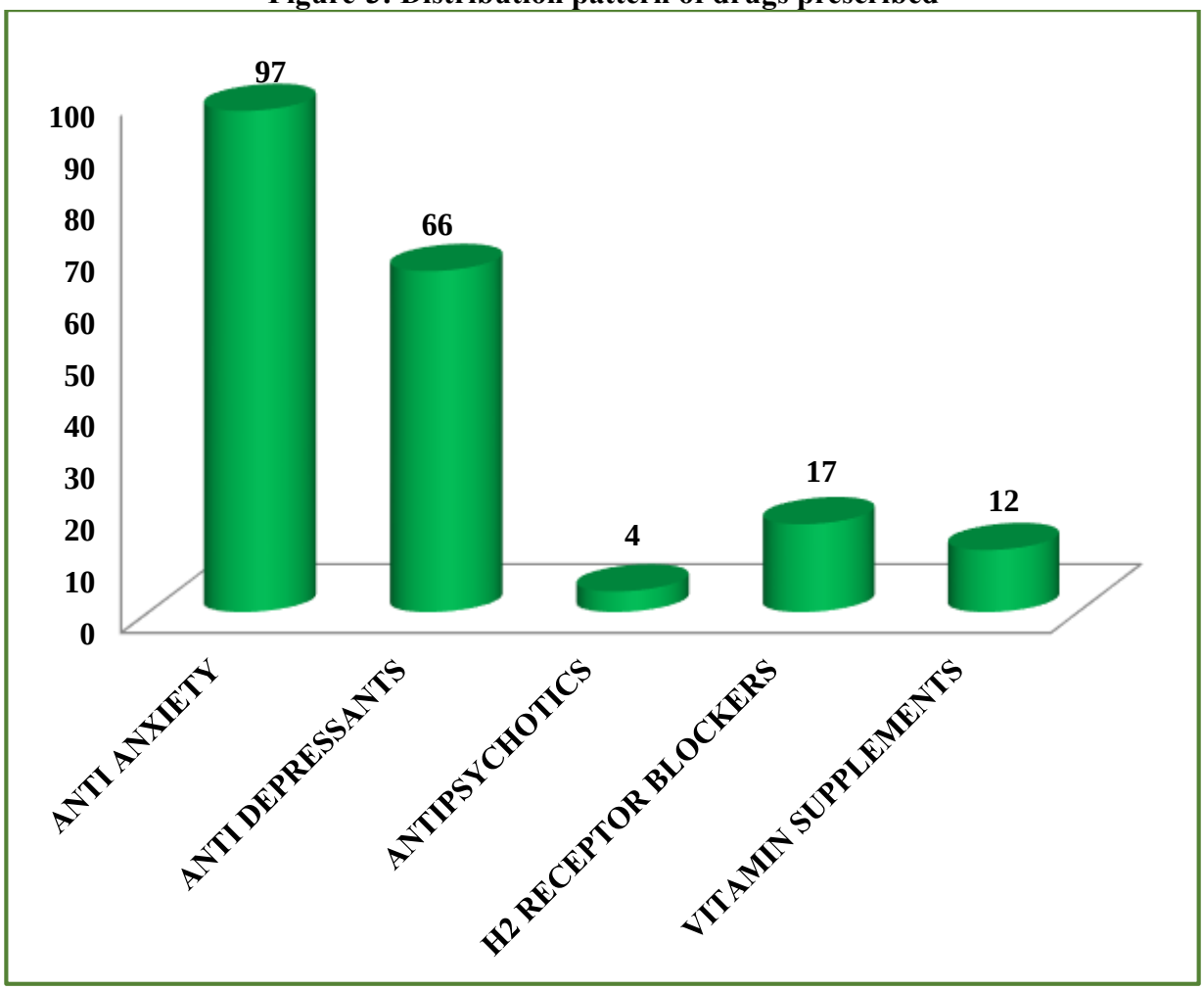


Figure-4: Observed prescription pattern in psychiatric disorders

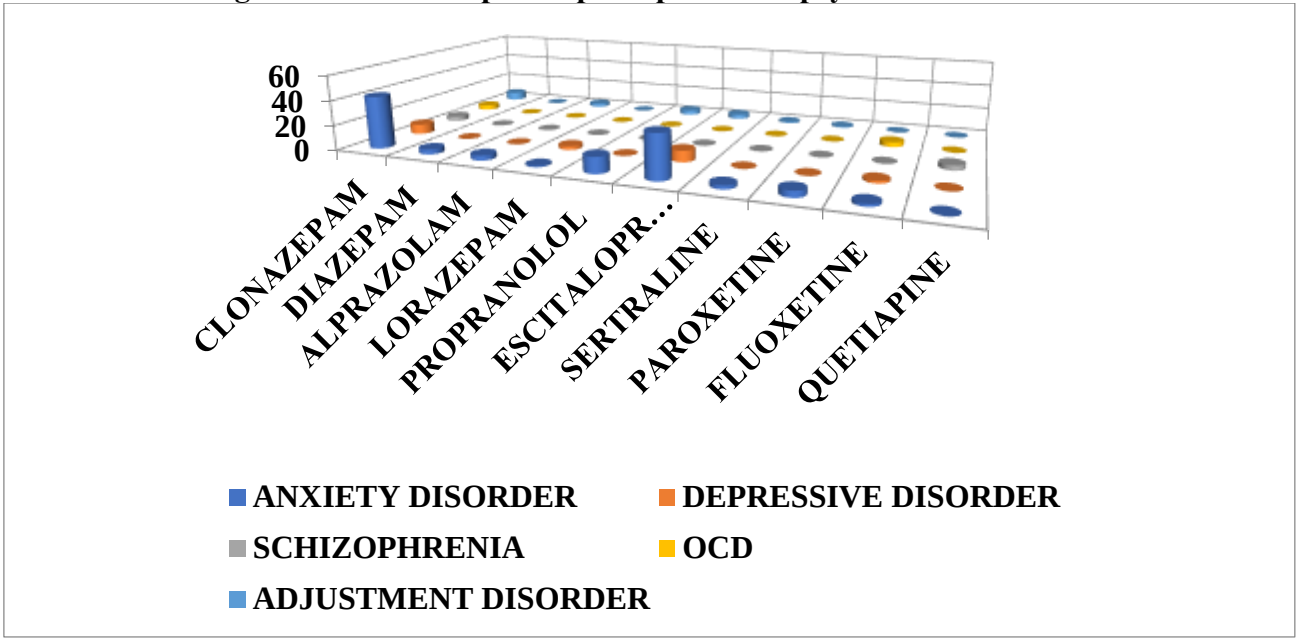


Table-7: Adverse effects encountered by patients during follow up

Adverse Effects	Total number	Drugs Responsible	Percentage (%)
Nausea	3	Escitalopram	6.25
	1	Clonazepam	1.53
Drowsiness	14	Clonazepam	21.53
	1	Alprazolam	14.28
Diarrhoea	1	Escitalopram	2.08
	1	Fluoxetine	12.5
Weight Gain	2	Paroxetine	33.33
Headache	4	Clonazepam	6.15
	1	Escitalopram	2.08