



A Drug Use Evaluation Study on Antidepressants in Psychiatric Patients at a Tertiary Care Teaching Hospital

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

Background: The pattern of prescribing Antidepressants to patients has been varying worldwide.
Objective: We aim to observe the prescribing pattern of antidepressants as well as assess its various outcomes in patients, the rationality of the prescriptions, and the prevalence of antidepressant usage.
Methodology: A prospective observational study of a total of 56 subjects receiving antidepressants was performed at the Psychiatry. They were screened for their various outcomes on using antidepressants. The written form of the medical record sheet was used to preserve the patient's Data. Prescription pattern, treatment chart, abnormal vitals were noted. Morisky's adherence scale was used to assess the adherence of patients to prescribed drugs. Hamilton depression rating scale was used to measure the patient's depressive stage. They were screened for possible ADRs.

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The causality and severity assessment of the observed ADRs was done by the WHO-UMC scale and Hartwig-Seigel scale respectively. Statistical analysis was done for all relevant data.

Results: In our study, the age of patients varies from 18 years to 85 years. The maximum number of patients were from the age group of 31-40 years [28.57% (N=16)]. The 50% (N=28) of patients were diagnosed with Depressive mood disorder. A total of 169 drugs were prescribed out of which 52.07% (N=88) were Antidepressant drugs. Out of 88 Antidepressant drugs, 20% (N=18) patients received Venlafaxine, followed by 17% (N=15) Escitalopram. Out of 56, 26.78% (N=15) showed low adherence, 41.07% (N=23) showed medium adherence and 32.14% (N=18) showed High adherence. 41.07% (N=23) patients were identified with drug use problems. Adverse drug reactions were suspected in 25% (N=14) patients. The most common type of Adverse reaction due to the drug was Weight gain (N=6 patients). Paroxetine drug was found with the highest number of ADRs 28.57% (N=4).

Conclusion: Most common antidepressant prescribed was Venlafaxine. Most Patients in the community included suffered from Depressive mood disorder with a maximum number of patients appeared from the age group of the thirties to forties. Patients due to their unstable mental status were adhering to therapy at medium levels. Drug use problem was identified commonly with patients on sedatives resulting them to either forget taking the pills or missing the dose. Patients generally had a common Adverse drug reaction of weight gain. Proper lifestyle modifications and patient counselling is required to benefit patient from treatment.

Keywords: Antidepressants; drug utilization; adverse drug reaction; medication adherence.

1. INTRODUCTION

The prevalence rate in the Indian population of psychotic disorders ranges from about 9.5-370/1000 populations [1]. Drug use evaluation (DUE) plays an important role in rationalizing the therapy. Rational drug prescribing is the process in which polypharmacy is avoided by using proper drugs which give the required therapeutic effect along with minimum possible side effects in the least time and also at an affordable price for patients [2]. The only purpose of DUE is to make sure that the drugs are utilized effectively with their correct and safe usage in the best patient healthcare. Every pharmacist plays an important role in the establishment of the DUE program. DUE is performed to inspect the aspects which are directly associated with medication use. DUE data helps in improving prescribing formulary compliance and patient compliance [3]. It is an essential component of medical audit and hence allows pharmacists to monitor and analyze the prescribing patterns of medicines, to make appropriate modifications in the prescribing patterns for rational therapeutic practice and also cost-effective patient care and also as a tool to study the clinical use of drugs in populations and its influence on our health-care system [4,5]. DUE aims to evaluate the rationality of therapy and to reach the goals, auditing methods for drug therapy regarding rationality. DUE may evaluate drug used at a population level, according to sex, age, morbidity, social class, among other

characteristics [6]. DUE also increases our understanding of how drugs are being used [7]. It also provides perception into the productivity of drug usage, i.e., whether a particular drug therapy gives value for money and the results of the research are used to help to set priorities for the rational administration of health care budgets [8]. We aim to observe the prescribing pattern of antidepressants as well as assess its various outcomes in patients, the rationality of the prescriptions, and the prevalence of antidepressant usage.

2. METHODOLOGY

It was a prospective observational study conducted for 6 months at the Department of Psychiatry, Dhiraj General Hospital, Vadodara. All patients between age 18 years to 85 years attending the department of psychiatry and diagnosed with any clinical condition as per DSM-5 criteria in which antidepressant drugs were prescribed were included in a study after explaining to the patients, the details of the study. The patient's medical records were checked and the following information was noted in the Patient Medical Record sheet: Patient's demographic details, Patient Medical History, Diagnosis and duration, family history, presence of other co-morbidities, Prescribed drugs including Antidepressants (Frequency, Dose, Route of administration and Duration) was also collected, Drug interaction, Cost of drugs, Lab investigations reports (which are already

mentioned inpatient medical records). All the relevant data was obtained from the patients' medical records and through counseling the patients who visited the Out- Patient Department (OPD) or In-Patient Department (IPD). Morisky's adherence scale was used to assess the adherence of patients to prescribed drugs. Hamilton depression rating scale was used to measure the patient's depressive stage. They were screened for possible ADRs. The causality and severity assessment of the observed ADRs was done by the WHO-UMC scale and Hartwig-Seigel scale respectively. All the relevant data collected and recorded electronically. Descriptive statistics used for the analysis of the data. After the data collection, all the data were exported to statistical software for statistical analysis. All the quantitative data were represented in mean ± standard deviation. Comparative statistical differences were calculated using appropriate parametric tests.

3. RESULTS

A total of 56 patients were included in the study. They were diagnosed with different types of Psychiatric illnesses like Depressive mood disorder, Anxiety, Panic disorder, Bipolar mood disorder- 1, Major depressive mood disorder, etc., and were further screened for various outcomes of antidepressants. Out of 56 patients, 25% (N=14) patients were affected by ADRs irrespective of their severity. Comparing the gender proportionality, male represents 64.29% (N=36) while female represents 35.71% (N=20). In our study, the age of patients varies from 18 years to 85 years with a mean age of 51 years. The maximum number of patients were from the age group of 31-40 years [28.57% (N=16)] followed by age group 41-50 years [23.21% (N=13)], and lastly, the least number of patients [1.78% (N=1)] were found in the age group of >70 years.

In our study, we noted that the maximum number of patients were diagnosed with Depressive mood disorder comprising 50% (N=28), followed by Major Depressive mood disorder with anxiety 16.07% (N=9), Major depressive disorder with 12.50% (N=7), Bipolar mood disorder-1 with 7.14% (N=4), and Anxiety with 3.57% (N=2). Various minor diagnoses included Panic disorder, Functional neurologic disorder, Dissociative mood disorder, Anhedonia, Severe depression with psychotic disorder, Tardive dyskinesia with 1.78% (N=1). Out of 56 OPD patients included Diagnosis pattern among

Population (Male and Female) showed that majority of males and female were diagnosed with Depressive mood disorder with 50% (Male N=18, Female N=10) respectively, followed by Major Depressive mood disorder with anxiety with 15% N=6 in Male and 16.66% [N=3] in Female), Bipolar mood disorder-1 with 11.11% (N=4) in males, Major depressive disorder with 11.11% (N=4) in males, 15%(N=3) in females And various Minor diagnosis included Functional neurologic disorder, Dissociative mood disorder, Anhedonia, Severe depression with psychotic disorder, Tardive dyskinesia with 2.77% (N=1) in Males and 5% (N=1) in females.

Table 1. Age group of study population

Age	Number of patients	Percentage (%)
<21	2	3.57%
21-30	9	16.07%
31-40	16	28.57%
41-50	13	23.21%
51-60	12	21.42%
61-70	3	5.35%
71-80	1	1.78%
Total	56	100.00%

According to the suspected diagnosis, medications were prescribed which contained Antidepressants along with other classes of medications. Of 56 OPD patients, a total number of drugs prescribed were 169 out of which 52.07% (N=88) were Antidepressant drugs and the remaining 47.92% (N=81) were drugs of class other than an antidepressant. Out of 56 patients included, 51.79% (N=29) of patients received 1 antidepressant drug in their prescription followed by 37.50% (N=21) of patients who received 2 antidepressant drugs, other data is mentioned in Table 4. Out of 56 patients prescribed with 88 Antidepressant drugs of various class, 20% (N=18) patients received Venlafaxine, followed by Escitalopram with 17% (N=15), Fluoxetine with 14% (N=12), Sertraline 13% (N=11), and other drugs of different antidepressant class are mentioned in Table 5. Out of 56 patients prescribed with 81 non-Antidepressant drugs of various class, 37.04% (N=30) patients received Clonazepam, followed by Olanzapine with 18.52% (N=15), Multivitamin with 9.88% (N=8), Lithium and Trifluoperazine with 6.17% (N=5), and other drugs of different non-antidepressant class are mentioned in Table 6.

Table 2. Diagnosis pattern among patients

Diagnosis	Numberof patients	Percentageof patients
Depressive mood disorder	28	50%
Major Depressive mood disorder with anxiety	9	16.07%
Panic disorder	1	1.78%
Anxiety	2	3.57%
Bipolar mood disorder-1	4	7.14%
Functional neurologic disorder	1	1.78%
Dissociative mood disorder	1	1.78%
Anhedonia	1	1.78%
Severe depression with psychotic disorder	1	1.78%
Tardive dyskinesia	1	1.78%
Major depressive disorder	7	12.50%
Total	56	100%

Table 3. Diagnosis pattern between patients (Male and Female)

Diagnosis	Male	Female	Percentage Male	Percentage Female
Depressive mood disorder	18	10	50%	50%
Major Depressive mood disorder with anxiety	6	3	16.66%	15%
Panic disorder		1	-	5%
Anxiety		2	-	10%
Bipolar mood disorder-1	4		11.11%	
Functional neurologic disorder	1		2.77%	
Dissociative mood disorder	1		2.77%	
Anhedonia	1		2.77%	
Severe depression with psychotic disorder		1		5%
Tardive dyskinesia	1		2.77%	
Major depressive disorder	4	3	11.11%	15%
Total	36	20	100%	100%

Table 4. Total no of antidepressants prescribed

Number of Antidepressant	Number of patients.	Percentage
1	29	51.79%
2	21	37.50%
3	5	8.93%
4	1	1.79%
5	1	1.79%
Total	56	100.00%

Drug-drug interactions are most common amongst Psychiatric patients. In our study, Drug-drug interactions were identified using a software database (E.g., Medscape and Micromedex interaction checker). Further, this interaction was identified in patients by a verbal discussion with patients noting the description of the event experienced. Out of 56 patients, Prescribed Antidepressants and Non-antidepressant drugs, 60.71% (N=34) patients did not experience any drug-drug interactions, however, 39.28% (N=28) patients experienced the interactions.

Drug use problems: For a psychiatric patient with altered mental status or imbalance in brain functions, using drugs prescribed might be a challenging thing. Drug using problems play an important role in treating a patient. In our study out of 56 patients, 41.07% (N=23) patients were identified. Cases of Drug dosing problem were identified with category a (wrong drug dose) where the patient took the wrong drug dose. 21 patients were categorized under Drug usage problem with category (Drug not taken at all, Wrong drug taken, Drug used without indication respectively).

Table 5. Number of antidepressants prescribed

Name of drugs	Number of patients	Percentage
Venlafaxine	18	20%
Escitalopram	15	17%
Fluoxetine	12	14%
Sertraline	11	13%
Dosulepin	8	9%
Paroxetine	7	8%
Bupropion	5	6%
Imipramine	3	3%
Desvenlafaxine	3	3%
Duloxetine	2	2%
Mirtazapine	2	2%
Trazadone	1	1%
Tianeptine	1	1%
Total	88	100%

Table 6. Number of non-antidepressant drugs prescribed

Name of drugs	Number of patients	Percentage
Clonazepam	30	36.14%
Olanzapine	15	18.07%
Multivitamin	8	9.63%
Lithium	5	6.02%
Trifluoperazine	5	6.02%
Pan-D	4	4.81%
Lorazepam	3	3.61%
Aripiprazole	2	2.40%
Tadalafil	2	2.40%
Petril-Beta	2	2.40%
Amisulpride	1	1.20%
Quetiapine	1	1.20%
Risperidone	1	1.20%
Divalproex sodium	1	1.20%
Sildenafil	1	1.20%
Famotidine	1	1.20%
Zolpidem	1	1.20%
Total	83	100%

Table 7. Drug-drug interactions among patients

Interactions in patients	Number	Percentage
No. of patients not experiencing interactions	34	60.71%
No. of patient experiencing interactions	22	39.28%
Total	56	100%

Table 8. Category of drug-drug interactions

Category	Total	Percentage
Minor	26	34.21%
Moderate	31	40.78%
Major	19	25%
Total	76	100%

Table 9. On basis of description of event, interactions experienced by the patients were listed as below

Effect of drug interaction on patient	Type of drug-drug interaction	Number of patients experiencing	Percentage
Sedation	Synergism	10	29.41
Agitation	Potentiation	7	20.58%
Confusion	Potentiation	6	17.64%
Sleep imbalance	Antagonism	3	8.82
Headache	Potentiation	1	2.94
Mood variations	Potentiation	2	5.88%
Anxiety attacks	Potentiation	2	5.88%
Hyperthermia	Potentiation	3	8.82%
Total		34	100%

Table 10. Drug use problems

Type of Drug use problem	Category	Total no. of drug use problems
Drug dosing Problem	Inappropriate drug	2
Drug usage problem	Drug not taken at all	15
	Wrong drug taken	4
	Drug used without Indication	2
Total		23

Adverse Drug Reactions: Based on the complaints and experiences of patients on consuming the drugs, out of 56 patients selected for the study ADR was suspected in 25% (N=14) patients. The remaining 75% (N=42) did not experience ADR. Out of 14 patients suspected of ADR, the most common type of Adverse reaction due to the drug was Weight gain (N=6 patients), followed by Tremors (N=2 patients), itching with burning sensation (N=2), Muscle weakness, and blackening of the skin. 14 people experiencing ADRs Paroxetine drug was found with the highest number of ADRs 28.57% (N=4) followed by Venlafaxine with 21.42% (N=3), Mirtazipine 14.28% (N=2), and other drugs like Divalproex, Olanzapine, Fluoxetine, Risperidone, and Lorazepam with 7.14% (N=1). Causality Assessment: Causality Assessment by WHO-UMC Causality Assessment was performed. By WHO-UMC Scale, out of 14 ADRs majority of ADRs were found to be Possible with 50% (N=7) followed by Probable with 28.57% (N=4) and Unclassifiable with 21.42% (N=3). Severity Assessment: The severity assessment of the major ADRs was carried out amongst which, Muscle weakness, weight loss, Itching and Blackening of skin, Itching and burning sensation was classified to be moderate and Jerky hand movements, weight gain, and EPS hand Tremors were classified as Mild according to Hartwig – Siegel scale. Morisky medication adherence scale was used to assess adherence. Based on their oral viva individual score was calculated.

Patients who scored ≥ 8 points, < 8 to > 6 points and ≤ 6 points on the scale were considered to have High, Medium, and Low Adherence respectively. Out of 56, 26.78% (N=15) showed low adherence, 41.07% (N=23) showed medium adherence and 32.14% (N=18) showed High adherence.

4. DISCUSSION

A total of 56 patients were included in the study according to the inclusion and exclusion criteria. Out of 56 patients, 25 % (N=14) patients were affected by ADRs. Out of 56 outpatients selected for the study Comparing the gender proportionality, male represents 64.29% (N=36) while female represents 35.71% (N=20) of the population. In our study, the age of patients varies from 18 years to 85 years with a mean age of 51 years. The maximum number of patients were from the age group of 31-40 years [28.57% (N=16)] followed by age group 41-50 years [23.21% (N=13)], and lastly, the least number of patients [1.78% (N=1)] were found in the age group of > 70 years in contrast to S. CHAKRABARTI et al. [9] with Majority of the sample were females (58%), half of them aged between 20-39 years, and a little more than a quarter (26%) in the age range of 40-49 years. According to the suspected diagnosis, medications were prescribed which contained Antidepressants along with other classes of medications. Of 56 OPD patients, a total number

of drugs prescribed were 169 out of which 52.07% (N=88) were Antidepressant drugs and the remaining 47.92% (N=81) were drugs of class other than an antidepressant. Out of 56 patients included, 51.79% (N=29) of patients received 1 antidepressant drugs in their prescription followed by 37.50% (N=21) of patients who received 2 antidepressant drugs, in contrast, to a study conducted by S. CHAKRABARTI et al. [9] where 64% (N=69) patients received 1 antidepressant drug and 18%(N=19) patients received 2 antidepressant

Table 11. Suspected ADRs

Patient Age	Sex	Suspected ADRs	Name of drug & class	Dose & Route of Administration	Frequency
34	Female	Itching and blackening of skin	Paroxetine Antidepressants	12.5 Mg PO	1-0-0
34	Female	Weight Gain	Paroxetine Antidepressants	12.5 Mg PO	1-0-1
55	Female	Muscle weakness	Lorazepam Benzodiazepine	2 Mg PO	0-0-1
	Male	Weight Gain	Risperidone Anti-psychotic	2 Mg PO	0-0-1
	Female	EPS hand Tremors	Fluoxetine Antidepressants	20 Mg PO	1-0-1
55	Female	Weight Gain	Mirtazapine Antidepressants	15 Mg PO	0-0-1
40	Female	Itching and burning sensation	Paroxetine Antidepressants	12.5 Mg PO	1-0-1
34	Female	Weight Gain	Olanzapine Antipsychotic	5 Mg PO	0-0-1
	Male	Hand tremors	Divalproex Anti-epileptic	500 Mg PO	1-0-1
43	Male	Jerky movement of hands	Venlafaxine Antidepressants	75 Mg PO	0-0-1
43	Male	Weight Gain	Venlafaxine Antidepressants	75 Mg PO	0-0-1
54	Male	Hand tremors	Paroxetine Antidepressants	12.5 Mg PO	0-0-1
32	Male	Weight Gain	Mirtazapine Antidepressants	7.5 Mg PO	0-0-1
	Male	Weight loss	Venlafaxine Antidepressants	75 Mg PO	0-0-1

Table 12. Drug and ADR prevalence

Name of Drug	Number	Percentage
Paroxetine	4	28.57%
Venlafaxine	3	21.42%
Mirtazapine	2	14.28%
Divalproex	1	7.14%
Olanzapine	1	7.14%
Fluoxetine	1	7.14%
Risperidone	1	7.14%
Lorazepam	1	7.14%

Table 13. Severity of ADRs

ADRs	Numbers of Patients	% Prevalence	Severity
Muscle weakness	1	7.14%	Moderate
Jerky hand movements	1	7.14%	Mild
EPS hand Tremors	3	21.42%	Mild
Itching and burning sensation	1	7.14%	Moderate
weight loss	1	7.14%	Moderate
weight gain	6	42.85%	Mild
Itching and blackening of skin	1	7.14%	Moderate
Total	14	100.00%	

Table 14. Adherence result

Score	Level of adherence	Number of patients	Percentage
≥8 points	High	18	32.14%
<8 to >6 points	Medium	23	41.07%
≤ 6 points	Low	15	26.78%

drugs. Antidepressants were prescribed in 52.07% prescriptions with 88 Antidepressant drugs of various class, 20% (N=18) patients received Venlafaxine, followed by Escitalopram with 17% (N=15), Fluoxetine with 14% (N=12), Sertraline 13% (N=11), and other drugs of a different antidepressant class lower than that of a study conducted by KingshukLahon, et al. [10] wherein Antidepressants were prescribed in 76.18% prescriptions (duloxetine -50%, escitalopram -22.40%, mirtazapine-17.19%, sertraline-6.77%, and others-3.64%). Drug-drug interactions are most common amongst Psychiatric patients. In our study, Drug-drug interactions were identified using a software database (E.g., Medscape and Micromedex interaction checker). Further, this interaction was identified in patients by a verbal discussion with patients noting the description of the event experienced. Out of 56 patients, Prescribed Antidepressants and Non-antidepressant drugs, 60.71% (N=34) patients did not experience any drug-drug interactions, however, 39.28% (N=28) patients experienced the interactions.

Based on the complaints and experiences of patients on consuming the drugs, out of 56 patients selected for the study, ADR was suspected in 25% (N=14) patients. The remaining 75% (N=42) did not experience ADR. Out of 14 patients suspected of ADR, the most common type of Adverse reaction due to the drug was Weight gain (N=6 patients), followed by Tremors (N=2 patients), itching with burning

sensation (N=2), Muscle weakness (N=1), and blackening of skin (N=1), Jerky hand movements (N=1) and Weight loss (N=1). Of 14 people experiencing ADRs Paroxetine drug was found with the highest number of ADRs 28.57% (N=4) followed by Venlafaxine with 21.42% (N=3), Mirtazapine 14.28% (N=2), and other drugs like Divalproex, Olanzapine, Fluoxetine, Risperidone, and Lorazepam with 7.14% (N=1) Higher than the result found in the study carried out by Munoli S., et al. [11] (5.2%), lower than that of the study conducted by Lucca JM., et al. [12] (34.24%) and Shah L., et al. [13] (32.8%). Causality Assessment by WHO-UMC Causality Assessment was performed by WHO-UMC Scale, out of 14 ADRs majority of ADRs was found to be Possible with 50% (N=7) followed by Probable with 28.57% (N=4) and Unclassifiable with 21.42% (N=3). in contrast to a study carried out by Shah A. et.al. in which maximum ADRs were classified 'probable' followed by 'possible'. No 'certain' causes were seen since in cases where DE-challenge was done, rechallenge was not attempted with the offending drug. This is following to study carried out by Munoli S. et al. [11] For 56 patients included in the study, the Morisky medication adherence scale was used to assess adherence. Based on their oral viva individual score was calculated. Patients who scored ≥8 points, <8 to >6 points and ≤ 6 points on the scale were considered to have High, Medium, and Low Adherence respectively. Out of 56, 26.78% (N=15) showed low adherence and 41.07% (N=23) showed medium adherence and

32.14% (N=18) showed High adherence, then study performed by Shrestha mandhar et al. [14] wherein Less number (37%) of the patients were adherent to the antidepressant therapy.

5. CONCLUSION

Our study shows that depressive mood disorder was the most common psychiatric diagnosis in the population and that out of antidepressants Most common antidepressant prescribed was Venlafaxine, followed by Escitalopram, Fluoxetine. Most Patients in the community included suffered from Depressive mood disorder with a maximum number of patients appeared from the age group 31-40 years. The preference for Venlafaxine over SSRIs as the first-line drug in depressive disorders did not conform to the standard prescribing guidelines. Most of the patients were treated with a single antidepressant. However, poor response and/or tolerability considerations made the prescribers change the antidepressant or add a second antidepressant. Antidepressants were prescribed for many indications other than depressive disorders and the psychiatrists' choice of the drug was influenced by the diagnosis, the severity of the disease/disorder, co-morbidity, drug efficacy, and the considerations for the patients' tolerability. The prescriptions were complete and polypharmacy was not seen. The consumption of antidepressants in the community was low. Adequate dosing was seen for all the antidepressants. Patients due to their unstable mental status were in majority of medium adherence levels (41.07%). Drug use problem was identified commonly with patients on sedatives resulting them to either forget taking the pills or missing the dose. Patients generally had a common ADR of weight gain. Proper lifestyle modifications and patient counseling is required to guide patient with mental instability and benefit them from treatment.

CONSENT AND ETHICAL APPROVAL

The study obtained ethical approval from the Sumandeep Vidyapeeth Institutional Ethics Committee (Ref no: SVIEC/IN/PHAR/BNPG18/D19005). And, the Informed consent form was taken from patients.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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