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Original Article

Prescribing Pattern and Adverse Drug Reaction Profiles in Patients with Bipolar Mood Disorder at A Tertiary Care Teaching Hospital

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ABSTRACT

Background: A combination of manic (bipolar mania), hypomanic (bipolar depression), and depressed (bipolar mania) episodes, together with notable subsyndromal symptoms that often manifest in between major mood episodes, describe bipolar mood disorder
Aim: To study the prescribing pattern and adverse drug reaction profiles in patients with bipolar mood disorder at a tertiary care teaching hospital.
Methods: This study was an observational, prospective and hospital -based cross sectional study conducted at Psychiatry department (both OPD & IPD) of Silchar Medical College and Hospital from March,2023-February,2024. 70 patients suffering from bipolar mood disorder were included.
Results: 46 patients (27.06%) were prescribed sodium valproate and 1 patient (0.58%) were prescribed carbamazepine. Among antidepressants, 6 patients (3.53%) were prescribed Fluoxetine and 7 patients (4.12%) were prescribed Sertraline. Most common combination drug sodium valproate + olanzapine was prescribed in 40% of the patients. Dry mouth occurred in 2 patients (3.92%), drowsiness occurred in drowsiness (13.73%), weight gain in 24 patients (47.06%) 3 patients (5.88%) had tremors, 12 patients (23.53%) had G.I upset and 3 patients (5.88%) had alopecia. Based on causality terms, 9 (17.65%) were classified as probable and 42 patients (82.35%) as possible. Based on severity of ADR, 42 patients (82.35%) were classified as mild and 9 patients (17.65%) as moderate.
Conclusion: Most commonly prescribed medication in patient with bipolar mood disorder in the Department of Psychiatry is the combination of Sodium Valproate & Olanzapine followed by the combination of Lithium, Olanzapine & Quetiapine. Existing data suggested that continuous administration of lithium, anticonvulsants & antipsychotics provides symptomatic relief in mood disorder & simultaneously causes various adverse drug reactions.

Keywords*: bipolar disorder; adverse drug reactions; prescribing pattern, anticonvulsants; antipsychotics.*

INTRODUCTION

A persistent, disabling mental illness is bipolar mood disorder (BMD). BMD is mostly treated with mood stabilizers and atypical antipsychotics. Adjunctive drugs like antidepressants and anxiolytics are also often utilized. Mood stabilizing medications are mostly used to treat bipolar mood disorder, both acutely and preventatively.[1,2] Sodium valproate, lamotrigine, carbamazepine, and lithium salts are among the medications that have the ability to stabilize mood. Similar characteristics apply to atypical antipsychotics in terms of preventing recurrence and acute episodes. They are often given in conjunction with propranolol, benzodiazepines, antidepressants, and mood stabilizers.[3] One factor that raises the risk of adverse drug reactions (ADRs) is polypharmacy. No matter how skillfully administered, all of the effective medications used for BMD treatment have the potential to cause negative side effects. Early identification of medication toxicity reduces therapy costs, improves patient compliance, and allows for prompt patient care. Information on adverse drug reactions (ADRs) resulting from psychiatric medicines is scarce in India.

Pharmacovigilance, or PV, is the pharmaceutical science of collecting, detecting, evaluating, monitoring, and preventing adverse drug reactions or drug-associated complication.[4] It outlines how ADR are tracked & assessed. It is an important component of clinical practice, public health initiatives, and effective drug control systems.[4]

World Health Organisation defined ADR as an undesired and unintentional reaction to a medication that typically happens at doses used in humans for disease prevention, diagnosis, treatment, or to alter physiological functions.[5] ADR monitoring is the practice of routinely keeping an eye out for any negative side effects that could be connected to taking medication. Even when a medication is administered sensibly, adverse drug reactions (ADRs) may still happen. No medicine is completely safe to use or in all people. The Center for Health Policy Research reports that over 50% of medicines that were authorized had some kind of unanticipated side effect that was not discovered before approval.[6] There are 9.5 to 370 mental diseases for every 1000 individuals in India. Twenty percent or more of adults suffer from one or more psychological disorders. They span from very severe kinds of diseases to subclinical stages.

In India, there is a high incidence of mental and behavioral disorders such as neurotic disorders, psychoses, alcohol and substance abuse, intellectual disabilities, and epilepsy. [7,8] The majority of mental diseases need for longer-term drug regimens that last anywhere from several months to years.[7,9] Extended treatment duration is linked to a variety of adverse drug reactions (ADRs). Because ADR monitoring takes non-adherence and relapse into account, it is very important. Facilitating the sensible use of pharmaceuticals by people is the main goal of drug use research. For each patient, rational drug usage means a prescription for a well-researched medication at the right dosage, with the right information, and at a reasonable cost. It is hard to start a conversation on responsible drug use or provide solutions to change prescribing practices if one is unaware of how medicines are prescribed and utilized.

It is difficult to get trustworthy national-level estimates of bipolar mood disorders in India since there haven't been many extensive investigations on the condition. This research project will be the first of its kind in Northeastern India. In light of this, this study was conducted with the purpose of analyzing the pattern of drug prescriptions as well as assessing the physical adverse drug reaction profiles with severity and causation of medications in BMD in order to assist healthcare providers and patients suffering from BMD in utilizing these medications rationally. The severity and causation of the ADRs were also evaluated.

AIM AND OBJECTIVES

AIM

To study the prescribing pattern and adverse drug reaction profiles in patients with bipolar mood disorder at a tertiary care teaching hospital.

OBJECTIVES

PRIMARY OBJECTIVES

1. To study the drug prescription pattern in patients suffering from bipolar mood disorder.
2. To assess the physical adverse drug reactions (ADR) of medications used in patients with Bipolar Mood Disorder.

SECONDARY OBJECTIVES

1) Evaluating the causality of adverse drug reactions using the standardized case causality assessment criteria developed by the World Health Organization Uppsala Monitoring Centre (WHO-UMC).

MATERIALS AND METHODS

1. Study subjects: Subjects included patients attending Psychiatry department (both OPD & IPD) of Silchar Medical College and Hospital.
2. Study period: One year from March, 2023 to February, 2024
3. Study design: Observational, cross-sectional, prospective study.
4. Study setting: Silchar Medical College & Hospital, Silchar, Assam
5. Sample size: Samples were drawn from the patients attending both OPD & IPD of psychiatry department of Silchar Medical College and Hospital in Silchar, Assam, in accordance with the fulfilment of inclusion and exclusion criteria, after getting approval from the Institutional Ethics Committee (IEC) of Silchar Medical College & Hospital, Silchar, Assam **.** Sample size is calculated by using Danial formula for sample size calculation:

$$N = \{Z^2 p(1-p)\}/d^2$$

Where:-

- N= Sample size
- Z= Statistics for a level of confidence (For the level of confidence of 95%, which is convention, Z Value is 1.96)
- p= expected prevalence is 3%
- d= precision (d is considered 0.04 to produce good precision and smaller error of estimate)

So, the sample size calculated to be

- N= 70 (patients with BPD was included serially for the study, after fulfilment of inclusion and exclusion criteria)

And equal number of (N=70) patients with BPD was included serially for the study, after fulfilment of inclusion and exclusion criteria.

6. Informed consent

Written voluntary informed consent was obtained from all study subjects after the study procedure was thoroughly explained to their satisfaction in both English and vernacular language The confidentiality, anonymity, and professional secrecy of all study subjects were maintained.

7. Ethical approval

Upon receiving approval and clearance from the IEC, the study was started (SMC/5834)

8. Inclusion criteria:

a. Patients with bipolar mood disorder attending both O.P.D. & I.P.D. of Psychiatry Department.
b. Patients of either sex aged between 18 to 60 years.
c. Patient or legal guardian willing to provide informed consent in writing and to follow up on a regular basis.
d. All patients with normal blood hemogram, normal blood sugar, normal lipid profile, normal ECG.

9. Exclusion criteria:

a. Pregnant and lactating women.
b. Patients who are already receiving treatment for bipolar mood disorder and visiting the SMCH outpatient department for review.
c. Patients with the epileptic disorder, mental retardation, presence of any cognitive impairment or suffering from any other major psychiatric illnesses (Schizophrenia, obsessive disorder).
d. Patient on electroconvulsive therapy.
e. Patients who are chronic alcoholic and drug abuse.
f. Patients having a history of allergic or serious adverse reactions to the study medications.
g. Patients with malignancies, severe diseases of the vital organs, adrenal or pituitary glands, severe impairments of the liver or kidneys, and terminally ill individuals.
h. Patients using drugs that are known to prolong the QT interval on an electrocardiogram or who may interact in some other way with the study drugs.

10. Study procedure:

Patients had a thorough history taking that included information on their demographics, personal and family history, previous and present medical history and drug history. The data were collected in Case Record Form. To gather any additional reliable data, the available case records were carefully examined. A thorough clinical assessment was conducted to:

a. determine the course, intensity, and duration of the illness
b. identify any underlying disease.

Both the prescription medicines and the use of concurrent medications were recorded. The prescription drug's generic name, doses, dosing regimen, and length of treatment were among the pharmaceutical data. The individuals were instructed to take their prescriptions on a regular basis at a specified time interval after completing the baseline exam. Patients were instructed to call the researcher and notify them right away if any adverse responses happened. In order to document the physical ADR, follow-up appointments were planned for the fourth, eighth, and twelfth weeks, respectively. Additional interim follow-ups might be arranged if necessary to evaluate adverse effects.

11. DATA COLLECTION PROCESS

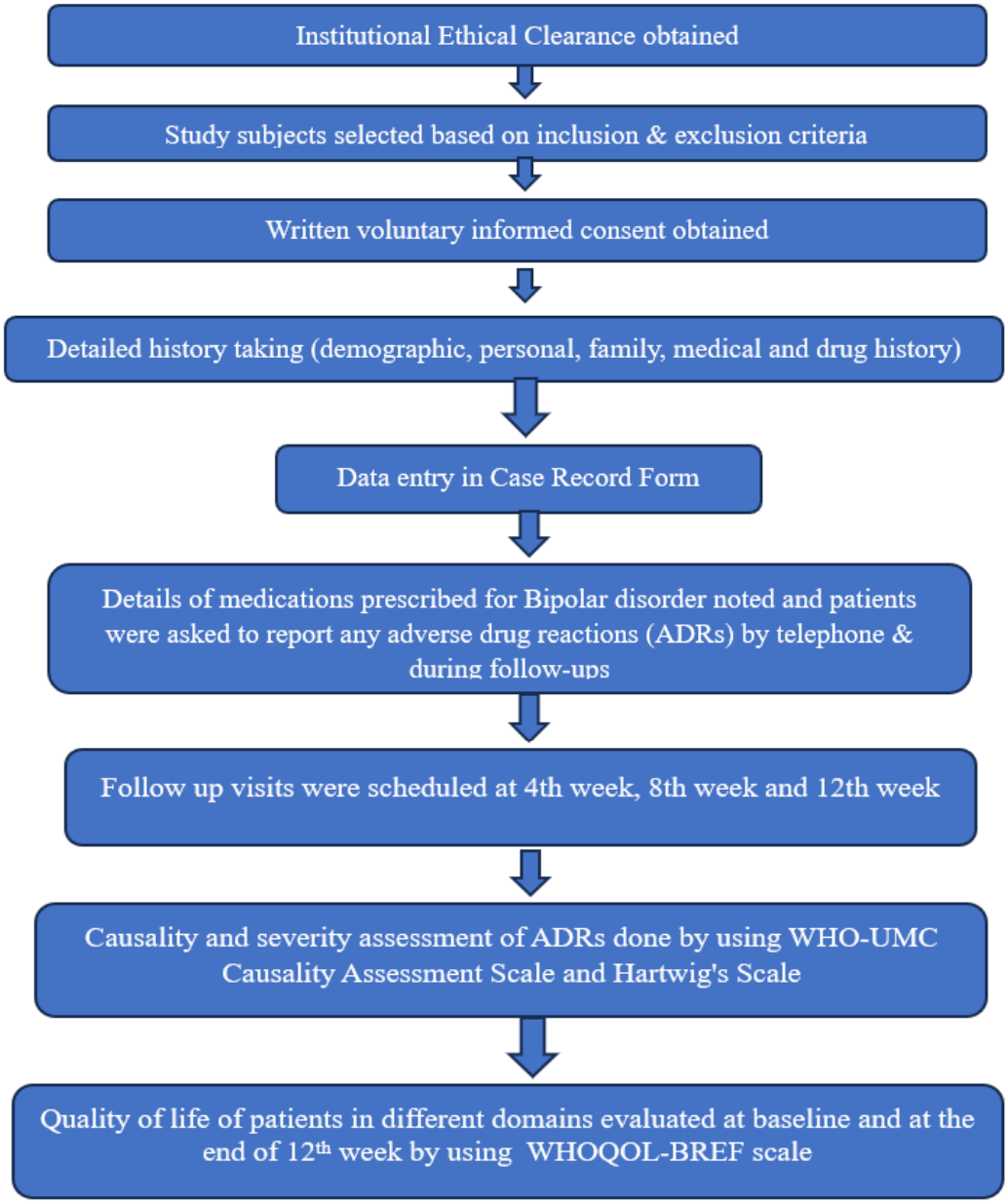

Figure 13: Data collection process

RESULTS

TABLE 1: DISTRIBUTION OF THE SUBJECTS BASED ON AGE GROUPS

Age Groups	Frequency	Percentage
18-30 yrs	31	44.29
31-40 yrs	27	38.57
41-50 yrs	8	11.43
51-60 yrs	4	5.71
Total	70	100
Mean Age (in years)	**33.14 ± 8.72**	

INFERENCE: The mean age of the patients was 33.14 ± 8.72 years. There were 31 patients (44.29%) in the 18-30 years age group, 27 patients (38.57%) in the 31-40 years age group, 8 patients (11.43%) in the 41-50 years age group, 4 patients (5.71%) in the 51-60 years age group.

TABLE 2: DISTRIBUTION OF THE SUBJECTS BASED ON GENDER

Gender	Frequency	Percentage
Males	42	60
Females	28	40
Total	70	100

INFERENCE: There were 42 males (60%) and 28 females (40%) in this study. There were 1.5 males for every 1 female.

TABLE 3: DISTRIBUTION OF THE SUBJECTS BASED ON RELIGION

Religion	Frequency	Percentage
Hindu	30	42.86
Muslim	37	52.85
Christian	3	4.29
Total	70	100

INFERENCE: 30 patients (42.86%) were Hindus, 37 patients (52.85%) were Muslims and 3 patients (4.29%) were Christians.

TABLE 4: DISTRIBUTION OF THE SUBJECTS BASED ON RESIDENCE

Residence	Frequency	Percentage
Urban	30	42.86
Rural	40	57.14
Total	70	100

INFERENCE: 30 patients (42.86%) were urban residents and 40 patients (57.14%) were rural residents.

TABLE 5: DISTRIBUTION OF THE SUBJECTS BASED ON SES*

Socio-economic Status (as per Modified Kuppuswamy Scale)	Frequency	Percentage
Upper	1	1.43
Upper Middle	9	12.86
Lower Middle	13	18.57
Upper Lower	30	42.86
Lower	17	24.28
Total	70	100

INFERENCE: According to Modified Kupppuswamy scale (2021), 1 patient (1.43%) belonged to upper SES, 9 patients (12.86%) belonged to upper middle SES, 13 patients (18.57%) belonged to lower middle SES, 30 patients (42.86%) belonged to upper lower SES, 17 patients (24.28%) belonged to lower SES.

TABLE 6: DISTRIBUTION OF THE SUBJECTS BASED ON EDUCATION

Education	Frequency	Percentage
Illiterate	14	20
Primary	12	17.14
Secondary	15	21.43
Higher Secondary & above	29	41.43
Total	70	100

INFERENCE: 14 patients (20%) were illiterates, 12 patients (17.14%) had primary education, 15 patients (21.43%) completed secondary education and 29 patients (41.43%) studied till higher secondary and above.

TABLE 7: DISTRIBUTION OF THE SUBJECTS BASED ON OCCUPATION

Occupation	Frequency	Percentage
Unemployed	10	14.29
Student	3	4.29
Housewife/ Homemaker	18	25.71
Agricultural worker	12	17.14
Non-Agricultural outdoor worker	19	27.14
Non-Agricultural indoor worker	8	11.43
Total	70	100

INFERENCE: 10 patients (14.29%) were unemployed, 3 patients (4.29%) were students, 18 patients (25.71%) were homemakers, 12 patients (17.14%) were agricultural workers, 19 patients (27.14%) were non-agricultural outdoor workers and 8 patients (11.43%) were non-Agricultural indoor workers.

TABLE 8: DISTRIBUTION OF THE SUBJECTS BASED ON MARITAL STATUS

Marital Status	Frequency	Percentage
Unmarried	19	27.14
Married	48	68.57
Divorced	3	4.29
Widowed	0	0
Total	70	100

INFERENCE: 19 patients (27.14%) were unmarried, 48 patients (68.57%) were married, 3 patients (4.29%) were divorced. In the present study, 48 patients (68.57%) were married.

TABLE 9: DISTRIBUTION OF THE SUBJECTS BASED ON SOCIAL HABITS

Social Habits	Frequency	Percentage
Non-smoker	46	65.71
Smoker	24	34.29
Total	70	100

INFERENCE: 46 patients (65.71%) were non smokers and 24 patients (34.29%) were smokers.

TABLE 10: DISTRIBUTION OF THE SUBJECTS BASED ON FAMILY TYPE

Family Type	Frequency	Percentage
Nuclear	39	55.71
Joint	31	44.29
Total	70	100

INFERENCE: 39 patients (55.71%) belonged to nuclear family and 31 patients (44.29%) belonged to joint family.

TABLE 11: DISTRIBUTION OF THE SUBJECTS BASED ON FAMILY HISTORY OF BIPOLAR DISORDER

Family history of Bipolar Disorder	Frequency	Percentage
Absent	39	55.71
Present	31	44.29
Total	70	100

INFERENCE: Out of 70 patients, 31 patients (44.29%) had a family history of bipolar disorder.

TABLE 12: DISTRIBUTION OF THE SUBJECTS BASED ON DRUGS PRESCRIBED IN BIPOLAR DISORDER

Drugs Prescribed in Bipolar Disorder		Frequency	Percentage
Lithium		23	13.53
Anticonvulsants	Sodium Valproate	46	27.06
	Carbamazepine	1	0.58
Atypical Antipsychotics	Olanzapine	63	37.06

	Risperidone	6	3.53
	Quetiapine	11	6.47
	Aripiprazole	7	4.12
Antidepressants	Fluoxetine	6	3.53
	Sertraline	7	4.12
TOTAL		170	100

INFERENCE: 23 patients (13.53%) were prescribed lithium. Among anticonvulsants, 46 patients (27.06%) were prescribed sodium valproate and 1 patient (0.58%) were prescribed carbamazepine. Among atypical antipsychotics, 63 patients (37.06%) were prescribed olanzepine, 6 (3.53%) were prescribed Risperidone, 11 patients (6.47%) were prescribed Quetiapine, 7 patients (4.12%) were prescribed arpiprazole. Among antidepressants, 6 patients (3.53%) were prescribed Fluoxetine and 7 patients (4.12%) were prescribed Sertraline.

TABLE 13: DISTRIBUTION OF THE SUBJECTS BASED ON CONCOMITANT DRUGS

Concomitant Drugs	Frequency	Percentage
Clonazepam	3	4.35
Lorazepam	23	33.33
PPIs (Pantoprazole)	26	37.68
Multivitamins & Multimineral	17	24.64
Total	69	100

INFERENCE: Concomitant drugs used were clonazepam in 3 patients (4.35%), Lorazepam in 23 patients (33.33%), PPIs (Pantoprazole) in 26 patients (37.68%) and Multivitamins & Multimineral in 17 patients (24.64%).

TABLE 14: DISTRIBUTION OF THE SUBJECTS BASED ON COMBINATION OF DRUGS PRESCRIBED IN BIPOLAR DISORDER

Combination of drugs Prescribed in Bipolar Disorder	Frequency	Percentage
Sodium Valproate + Olanzapine	28	40
Lithium + Olanzapine + Quetiapine	8	11.43
Sodium Valproate + Olanzapine + Fluoxetine	6	8.57
Sodium Valproate + Olanzapine + Sertraline	6	8.57
Lithium + Olanzapine + Risperidone	5	7.14
Lithium + Aripiprazole	5	7.14
Lithium + Olanzapine	5	7.14
Sodium Valproate + Olanzapine + Quetiapine	3	4.29
Sodium Valproate + Olanzapine + Aripiprazole	2	2.86
Sodium Valproate + Risperidone	1	1.43
Carbamazepine + Sertraline	1	1.43
Total	70	100

INFERENCE: Sodium Valproate + Olanzapine in 28 patients (40%), Lithium + Olanzapine + Quetiapine in 8 patients (11.43%), Sodium Valproate + Olanzapine + Fluoxetine in 6 patients (8.57%), Sodium Valproate + Olanzapine + Sertraline in 6 patients (8.57%), Lithium + Olanzapine + Risperidone in 5 patients (7.14%), Lithium + Aripiprazole in 5 patients (7.14%), Lithium + Olanzapine in 5 patients (7.14%), Sodium Valproate + Olanzapine + Quetiapine in 3 patients (4.29%), Sodium Valproate + Olanzapine + Aripiprazole in 2 patients (2.86%), Sodium Valproate + Risperidone (1.43%) in 1 patient and Carbamazepine + Sertraline in 1 patient (1.43%).

TABLE 15: BASELINE CHARACTERSTICS

Clinical Examination (At Baseline Visit)	Mean (+ SD)
Body weight (in kg)	53.94 **(± 10.09)**
Pulse (bpm)	80.95 **(± 10.35)**
SBP (mm of Hg)	111.01 **(± 10.53)**
DBP (mm of Hg)	**73.42 (± 8.18)**

INFERENCE: The mean body weight (in kg) was 53.94 (± 10.09) kgs, mean pulse was 80.95 (± 10.35) bpm, mean SBP was 111.01 (± 10.53) mm Hg, mean DBP (mm of Hg) was 73.42 (± 8.18) mmHg.

TABLE 16: BASELINE INVESTIGATIONS

Investigations (At Baseline Visit)		Mean (± SD)
Haemoglobin (g%)		11.46 (± 1.17)
TLC (cells/mm^3)		6198.42 (±1201.92)
DLC (%)	Neutrophil	61.04 (± 6.68)
	Lymphocyte	31.04 (± 6.39)
	Monocyte	5.04 (± 1.63)
	Eosinophil	2.74 (±1.24)
	Basophil	0.257 (± 0.471)
ESR (mm/hr)		12.97(± 2.42)
RBS (mg/dl)		119.18 (± 6.48)
LFT	Total Bilirubin (mg/dl)	0.56 (± 0.15)
	Direct Bilirubin (mg/dl)	0.16 (± 0.06)
	SGOT (IU)	25.84 (± 7.21)
	SGPT (IU)	36.28 (± 11.69)
	ALP (IU)	107.95 (±23.72)
KFT	Blood Urea (mg/dl)	12.15 (± 3.05)
	Serum Creatinine (mg/dl)	0.62 (±0.20)
Serum Lipid Profile	Serum Total Cholesterol (mg/dl)	153.05 (±17.39)
	Serum Triglyceride (mg/dl)	122.34(± 12.88)
	Serum VLDL (mg/dl)	21.54 (±13.38)
	Serum LDL (mg/dl)	73.35 (± 12.12)
	Serum HDL (mg/dl)	58.15 (± 8.86)
ECG		No abnormality seen in any patients

INFERENCE: The mean haemoglobin (g%) was 11.46 (± 1.17); mean TLC (cells/mm^3) was 6198.42 (±1201.92); mean neutrophil count was 61.04 (± 6.68), mean lymphocyte was 31.04 (± 6.39), mean monocyte was 5.04 (± 1.63), mean eosinophil was 2.74 (±1.24) and mean basophil was 0.257 (± 0.471). The mean ESR (mm/hr) was 12.97(± 2.42). The mean RBS (mg/dl) was 119.18 (± 6.48).

Based on LFT, total Bilirubin (mg/dl) was 0.56 (± 0.15), direct Bilirubin (mg/dl) was 0.16 (± 0.06), SGOT (IU) was 25.84 (± 7.21), SGPT (IU) was 36.28 (± 11.69) and ALP (IU) was 107.95 (±23.72). Based on KFT, Blood Urea (mg/dl) was 12.15 (± 3.05) and Serum Creatinine (mg/dl) was 0.62 (±0.20). Based on Lipid Profile, Serum Total Cholesterol (mg/dl) was 153.05 (±17.39), Serum Triglyceride (mg/dl) was 122.34(± 12.88), Serum VLDL (mg/dl) was 21.54 (±13.38), Serum LDL (mg/dl) was 73.35 (± 12.12) and serum HDL (mg/dl) was 58.15 (± 8.86). No ECG abnormality seen in all patients.

TABLE 17: DISTRIBUTION OF THE SUBJECTS BASED ON ADVERSE DRUG REACTIONS

Adverse Drug Reaction (ADR)	Frequency	Percentage
Dry mouth	2	3.92
Urinary retention	0	0
Drowsiness	7	13.73
Increased appetite	0	0
Weight gain	24	47.06
Tremors	3	5.88
Dizziness	0	0
Sexual distress (erectile dysfunction, premature ejaculation)	0	0
Hypersensitivity	0	0
G.I. Upset (nausea, vomiting, bloating, diarrhoea or constipation, epigastric distress)	12	23.53
Anxiety	0	0
Insomnia	0	0
Alopecia	3	5.88
Total	51	100

INFERENCE: Dry mouth occurred in 2 patients (3.92%), drowsiness occurred in drowsiness (13.73%), weight gain in 24 patients (47.06%) 3 patients (5.88%) had tremors, 12 patients (23.53%) had G.I upset and 3 patients (5.88%) had alopecia.

TABLE 18: DISTRIBUTION OF THE SUBJECTS BASED ON CASUALITY

Causality Terms	Frequency	Percentage
Certain	0	0
Probable	9	17.65
Possible	42	82.35
Unlikely	0	0
Total	51	100

INFERENCE: Based on causality terms, 9 (17.65%) were classified as probable and 42 patients (82.35%) as possible.

TABLE 19: DISTRIBUTION OF THE SUBJECTS BASED ON SEVERITY OF ADR

Severity	Frequency	Percentage
Mild	42	82.35
Moderate	9	17.65
Severe	0	0
Total	51	100

INFERENCE: Based on severity of ADR, 42 patients (82.35%) were classified as mild and 9 patients (17.65%) as moderate.

TABLE 20: ANALYSIS OF PRESCRIPTION PATTERN AS PER WHO CORE PRESCRIBING INDICATORS:

Parameters/Indicators	Frequency
Total no. of drugs prescribed	239
Total no. of Drugs used in bipolar disorder	170
Average number of drugs used in bipolar disorder per prescription	2.4285
Percentage of drugs used for bipolar disorder prescribed by generic names	100%
Percentage of encounters with an antibiotic prescribed	0
Percentage of encounters with an injection prescribed	0
Percentage of drugs used in bipolar disorder prescribed from NLEM 2022	41.18%

INFERENCE: The total no. of drugs prescribed were 239. The total no. of drugs used in bipolar disorder were 170. Average number of drugs used in bipolar disorder per prescription were 2.4285. Percentage of drugs used for bipolar disorder prescribed by generic names was 100%. Percentage of drugs used in bipolar disorder prescribed from NLEM 2022 were 41.18%.

DISCUSSION

In order to examine the medication prescription patterns and evaluate the physical adverse drug reaction(ADR) profiles of patients with bipolar mood disorder(BMD) in a tertiary care teaching hospital, the current research was conducted at Silchar Medical College & Hospital in Silchar, Assam. In our nation, the scope of pharmacovigilance is continuously growing. Pharmacovigilance data is often accessible globally for individual medications or drug groups; however, data about adverse drug reactions (ADRs) in particular illnesses is scarce. A widespread, recurring, and usually incapacitating mental illness is bipolar disorder.[13] The substantial side effects of the medications used for the management of BPD lower patient compliance and increase treatment costs.[13] Patients with bipolar mood disorder attending both O.P.D. & I.P.D. of the Psychiatry Department were included in our study.

Bipolar disorder has two peaks in onset age, according to Jain A et al.: from 15 to 24 years as well as from 45 to 54 years. Before 25, almost 70% of individuals experience the illness's clinical symptoms. [14] The majority of patients (44.29%) in this research were aged 18 to 30 years, with 33.14 ± 8.72 years as the mean age. Males accounted for sixty percent of the patients. These results were consistent with those of Shah A et al., who found that the mean age of the 65.56% of men in their group was 37.94±12.85 years.[10] The majority of patients (57.4%) in different research by Safal NK et al. were found to be between the ages of 21 and 40, and 71.25% of them were men.[15] A research by Grover et al. revealed a male prevalence of 63.6% of patients. One of the likely causes is that the male family members have the major position of earning the family's income and serving as its defender and decision-maker. When a male family member becomes unwell, their ailments are often given more attention, and they tend to seek medical attention quickly; this is not necessarily the case for female family members.[11]

Similar to this, the hypothesis proposed by Ellison and Levin stated that measuring the variance in religious participation by state of Bipolar Mood Disorder might be useful in identifying whether or not people with BPD use religion as a coping mechanism for dysfunctional BPD states.[16] Of the patients in this research, Hindus made up the majority (42.86%). However, in another study conducted by Stroppa et al., 53.6% of the subjects were Christians.[17]

According to Rowland TA, BPD is more common in cities than in rural regions.[18] Nonetheless, the bulk of survey participants (57.14%) came from rural areas. On the other hand, we found that 30 patients (42.86%) were from upper-lower SES.

According to a Dutch study done by Vreeker A et al. and MacCabe et al., individuals diagnosed with BPD type I were more inclined than controls to attain higher education, and those who excelled academically were found to be four times as likely to develop BPD compared to those with average qualifications.[19,20] In contrast to the general population, those with bipolar mood illness had a comparable degree of education but a poorer social standing, according to a Norwegian research by Schoeyen HK et al.[21] Similar to this, the majority of patients (41.43%) in the current research were literate at or above upper secondary.

Because occupational impairments account for 80% of vocational impairments and unemployment at 65%, it is one of the most troublesome impairments for BPD people. [22] In the current study, non-agricultural outside workers made up 19 patients (27.14%), followed by homemakers, who made up 18 patients (25.71%). Similarly, employment rates in BD varied from 40 to 75 percent in different research conducted by Dominiak M et al. [23]

According to Grover et al., a significant number of BPD patients marry, and their divorce rates are greater.[24] Nevertheless, 48 patients (68.57%) in the current research were married, and only 4.29% were divorced. Conversely, a different research by Vajawat B et al. revealed that BPD patients had greater divorce rates.[25]

Most mental disorders have been linked to cigarette smoking as a risk factor. According to Yuan, S. et al., smoking cigarettes is linked to a higher risk of certain mental conditions like BD, major depressive disorder, suicide.[26] In the current research, however, 34.29% of the patients smoked, whereas the majority of patients (65.71%) did not smoke.

Thirty-one patients (44.29%) and 39 patients (55.71%) in the current research belonged to joint families. These results were consistent with a research by Dhiman S. et al. that found 54% of BD patients came from nuclear households.[27]

Globally, bipolar disorder (BD), a highly inheritable psychiatric condition, is thought to impact about 50 million individuals.[28] It has been observed that BD patients & their families exhibit high levels of emotional expressiveness, a deficiency in interpersonal relationships, and a lack of cohesion and adaptability. [29] Thirty individuals (44.29%) out of the seventy in the current research had a positive family history.

Mood stabilizer are the most frequently prescribed medications for BD, both acutely and preventatively. [12] Traditionally, the first-line or primary treatment for BD has been lithium.[15] Safal AK noted that in their investigation, lithium was the mood stabilizer that was administered the most (47.5%). [15] A distinct study by Levine J et al. found that 47% of patients received lithium treatment.[30] In the current research, lithium was administered to only 13.53% of patients.

Olanzapine was found to be the most often prescribed antipsychotic (38.8%) by Safal NK.[15] Olanzapine was used to treat 37% of patients, according to research by Lim PZ et al.[31] These findings were consistent with the current investigation, which found that 37.06% of patients receiving atypical antipsychotics were administered olanzepine. A new study conducted by Lin SK et al. revealed a drop in the prescription rates of lithium and an increase in valproic acid.[32] Of the patients receiving anticonvulsants in the current research, 46 (27.06%) received sodium valproate prescriptions, and 1 (0.58%) received carbamazepine prescriptions. Six patients (3.53%) received fluoxetine prescriptions, while seven patients (4.12%) received sertraline prescriptions among the antidepressants.

Consequential medications (n = 93) were prescribed in a study by Parmar et al. These included 25 (26.88%) multivitamins, 17 (18.28%) endocrine medications (anti-diabetic and hormone replacement medications), 14 (15.05%) antihypertensive and antacid medications, 8 (8.60%) antimicrobial medications, and 15 (16.13%) other medications (steroids and anticoagulants).[12] PPIs (Pantoprazole) were used as concurrent medications in 26 patients (37.68%), Lorazepam in 23 patients (33.33%), Multivitamins & Multimineral in 17 patients (24.64%), and Clonazepam in 3 patients (4.34%) in the current study.

A mood stabilizer and an antipsychotic are administered to 28% and 27.8% of patients, respectively, in research by Musetti et al. and Grover et al.[33] [24] Similarly, 40% of the patients in this research were administered the most popular combo of olanzapine and sodium valproate. Patients treated by Trivedi et al. used this combination less often.[34] In their study, Walpoth-Niederwanger et al. evaluated changes in prescription patterns over a nine-year period. They found that the use of this combination increased for manic episodes from 64.1% (1999–2003) to 78% (2004–2007) and for mixed episodes from 57.5% (1999–2003) to 60% (2004–2007).[35]

According to Shah A et al., the study population's mean bodyweight was 58.63±9.07 kg.[10] In the current investigation, the average body weight (in kilograms) was 53.94 (± 10.09) kg, the average pulse was 80.95 (± 10.35) bpm, the average SBP was 111.01 (± 10.53) mm Hg, and the average DBP (in millimeters of mercury) was 73.42 (± 8.18) mmHg. In the current research, baseline blood examinations were normal for every patient.

According to Shah A et al., asthenia was the most frequent adverse drug reaction (ADR), other ADRs included weight gain, sedation, , extrapyramidal side effects (EPS), tremors, polyuria/polydipsia. This can be the result of a pharmacological effect extension of the medications used in bipolar illness management.[10] De Bragança AC in their study showed that carbamazepine is effective in treating lithium-induced Nephrogenic Diabetes Insipidus (NDI). [36] Women were more likely than males to have hypothyroidism, according to a research by Ahmadi-Abhari SA et al.[37] In patients with severe depressive illness, fluoxetine was linked to the majority of instances of sexual dysfunction in both men and females, according to a randomized controlled study conducted by Khazaie H et al. [38]. In the current study, 24 patients (47.06%) gained weight, 12 patients (23.53%) had G.I. upset, 7 patients (13.73%) experienced tiredness, 3 patients (5.88%) experienced tremors, 3 patients (5.88%) experienced alopecia, and 2 patients (3.92%) experienced dry mouth. Shah A et al found that either the medication was discontinued or the dosage was lowered in patients with GI problems, anemia, acne, and alopecia.[10]

42 cases (82.35%) were assessed as possible and 9 (17.65%) as likely based on evaluations of causation. Studies by Shah A et al., Sengupta et al., Lahon K et al., on the other hand, found that most of the instances were "probable." [10][39.40] According to Shah et al., the most common responses were mild to moderate intensity. [9] Similar to this, 42 patients (82.35%) in the current research were categorized as mild and 9 patients (17.65%) as moderate according to the severity of ADR.

There were 239 medications prescribed in total. Of these, 170 were primarily used for the treatment of BMD. Average number of prescription medications taken for bipolar illness was 2.4285. 100% of the medications used for BMD treatment were prescribed under generic names. The percentage of NLEM 2022 medications given for bipolar illness was 41.18%. In a similar manner. Grover et al. found that patients receiving continuation phase therapy are prescribed more drugs overall, with benzodiazepines and antipsychotics being the most common. In addition, in addition to the standard mood stabilizers and/or antipsychotics, some of the patients more often also took antidepressants.[24]

CONCLUSION

Our study aimed to sensitize the healthcare providers and also the patients about the possible misuse of drugs as well as avoidable harm done by different type of adverse drug reactions. Present study shows that most commonly prescribed medication in patient with Bipolar Mood Disorder(BMD) in the department of psychiatry is the combination of Sodium Valproate & Olanzapine followed by the combination of Lithium, Olanzapine & Quetiapine. Existing data suggested that continuous administration of lithium, anticonvulsants & antipsychotics provides symptomatic relief in mood disorder & simultaneously causes various Adverse drug reactions. The study setting performed well in terms of the average number of prescription medications for BD under generic names, percentage of prescriptions that included injections and antibiotics, and was in line with the WHO optimal values of these indications, nevertheless it fell short of recommendation in terms of writing prescriptions that contained NLEM drugs, which indicates a scope of improvement for including more NLEM drugs while writing prescription.

This study has particular significance in that it describes the pattern of physical adverse drug reactions that bipolar disorder patients experience. We may infer from this study that physical ADR happen relatively often in BMD patients, are generally mild and are more typically linked to the mood stabilizer sodium valproate & the atypical antipsychotics olanzapine. Weight gain was the commonest ADR followed by dry mouth, GI upset, drowsiness, tremors and alopecia.

Therefore, identifying these ADRs and managing them helps guarantee the patient receives the best treatment possible while lowering them. These prospective studies, carried out in many institutions with the active participation of pharmacologists and psychiatrists, might be useful in creating a database for adverse drug reactions (ADRs) related to psychiatric medications. ADR may lead to a higher rate of hospitalization as well as longer hospital stays, which can raise the financial and psychological burden of care. It highlights how important it is for treating doctors to adopt a pharmacovigilance mindset in order to accurately track adverse drug reactions (ADRs) brought on by every medication used to treat bipolar illness. The analysis will be much more sufficient and accurate if all of the pharmacovigilance data, including the patient follow-up information, is available.

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AUTHORS CONTRIBUTIONS

Nivedita Saha: One of the researchers that came up with the study concept and research topic. Moreover, being involved in the design of the study, defining intellectual content, searching the literature, obtaining and analyzing data, she was also involved in preparing and editing manuscript, and also reviewing it. Dolly Roy: One of the developers of the study's concept. In addition, she had also contributed in the design of the study, defining the intellectual contents, searching the literature, acquiring data, preparing and reviewing the manuscript, and supervised all phases of the research process. Prosenjit Ghosh: One of the authors who came up with the study's framework, was also involved in data collection, literature search, study design, intellectual content definition, collecting data, and manuscript writing.

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