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A Prospective Observational Study On Clinical Profile And Drug Utilisation Review In Bipolar Patients Using Antipsychotic, Antidepressants And Mood Stabilizer Medications In Psychiatry Unit Of A Tertiary Care Hospital

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Abstract

Background*: Bipolar disorder is a psychiatric disorder, which is a pattern that causes distress or impairment of personal functioning. It is a multifactorial illness with uncertain aetiology or illness having episodes of severe mood disturbances, neurological deficits and disturbances in functioning.*

Materials and Methods: *A Prospective Observational study was conducted for 6 months at Psychiatric unit of a Government General Hospital Kurnool. Total of 154 patients included who were taking Antipsychotics, Antidepressants, Mood stabilizer Medications based on exclusion and inclusion criteria to analyse the Clinical profile and Drug utilisation review by using Microsoft Excel and Prism8 software.*

Results: *In our prospective study of 154 patients with Bipolar disorder and taking Antipsychotics, Antidepressants, Moodstabilizer medications are observed. The study showed that females (51.3%) are more prone to the disorder than the males (48.7%) based on the gender. The age distribution represents that majority of them were 25-45years. Among the 154 patients included in the study 374 adverse effects were noted in male and 337 adverse effects were noted in females who were using single drug therapy, and combination therapy of two drug combination and three drug combination.*

Conclusion: *We observed age, gender, education level, residence, treatment adherence, symptoms, treatment, and adverse reactions. Clinical profile and Drug utilisation review helps in changing trends and has become a popular tool to be used in evaluation of health systems. Reporting of Adverse reactions enhance the patients compliance, decreased morbidity and contribute to patient safety.*

Key words: *Bipolar disorder, Psychiatric Unit, Prospective Study, Drug utilisation review, Clinical profile.*

I. Introduction

According to DSMIV criteria, mental disorder is a psychological syndrome or pattern which is associated with distress, disability, increased risk of death.

Unlike the DSM and ICD, some approaches are not based on identifying distinct categories of disorder using dichotomous symptom profiles to separate abnormal from the normal According to DSMV criteria and American psychiatric association depression is the most common illness, which is on the rise globally and is the major depressive disorder or also called as clinical depression which is also called as unipolar depression characterized by low mood, aversion to activity that affectsBipolar disorder is a severe and often relapsing mental disorder that is characterized by abnormal mood and behaviours that dramatically impair functioning; this disorder is associated with episodes of mood swings ranging from depression to mania. It is also known as manic depressive illness that causes unusual shifts in mood, energy, activity levels, and the ability to carry out day to day tasks. The person may experience periods of depression and abnormally elevated moods. The elevated mood is known as Mania, the symptoms of mania are abnormally energetic, happy, irritable, reduced need for sleep and loss of touch with reality. Bipolar disorder is a multi factorial illness with uncertain aetiology or multi component illness involving episodes of severe mod disturbance, neuropsychological deficits and disturbances in functioning. It is the leading cause of disability worldwide. There are four basic types of bipolar disorder ;all of them involve clear change in mood ,energy , and activity levels .These mood range from periods of extremely up elated and energized behaviour (know as manic episodes) to very sad down or up elated and energized behaviour to very sad down or hopeless periods. Less severe manic periods are known as hypo manic

episodes. The bipolar disorder is classified into two types based on the mood and energy: Bipolar I disorder defined by manic episodes that last at least 7days, or by manic symptoms that are severe that the person need immediate hospital care .Usually depressive episodes occurs as well, typically lasting at least 2 weeks. Episodes of depression with mixed features are also possible. The prevalence of bipolar type1 is around 1%in the general population. A large cross sectional survey of 11 countries found the overall lifetime prevalence of bipolar spectrum disorders was 2.4% with prevalence of 0.6% for bipolar type 1.Bipolar II disorder defined by a pattern of depressive episodes and hypo manic episodes, but not the full blown manic episodes .A large cross –sectional survey of 11 countries found the overall lifetime prevalence of bipolar spectrum disorders was 2.4 % with a prevalence of 0.4% for bipolar type II. The bipolar disorder is treated with medications such as mood stabilizers ,anti depressants ,anti psychotics and psychotherapy .Mood stabilizers include lithium and certain anti convulsants such as sodium valproate, carbamazepine. The anti psychotics and anti depressants are psychotropic medications which are used for the treatment of bipolar disorder. Clinical profiles include the details of the patient regardless to age, gender, name etc,.

II. Materials And Methods

Study Site: Government General Hospital, Kurnool.
Study Period: The study was carried out for 6 months i.e., from June 2019 to November 2019.
Sample Size: During this period 154 cases were collected based on the inclusion and exclusion criteria.

Inclusion Criteria
Patients diagnosed with bipolar disorder and who are treated with Antipsychotics, Antidepressants and Mood stabilizer medications. Patients of age >18 years are included in the study. Either gender is considered.
Exclusion Criteria
Patients who are not diagnosed with bipolar disorder and taking other than allopathic drugs are excluded. Patients of age <18 years are excluded in the study.
IRB Approval
The research protocol was duly approved by IRB of Dr.K.V.Subba Reddy institute of pharmacy vide approval number KVSP/IRB/2019-2020/Pharm.D/PROJ/12.
Method of study
Selection of the patient was based on the inclusion and exclusion criteria. All data is collected using a patient profile proforma. Adverse drug reactions were calculated and reviewed using Naranjo's scale. The data was analysed by using Microsoft Office Excel, Prism 8 software.

III. Results

A total of 154 patients were enlisted in the study are presented from the outpatient department , in which 68 patients represented with depression, and 86 patients represented with mania.

AGE DISTRIBUTION IN PATIENTS:-

A total of 154 patients presented to the outpatient department, among which majority of the patients were found between the age group 25- 35 years (46 patients), followed by 18-25 years (30 patients) patients, 35-45 years (38 patients), 45-55 years (21 patients), 55-65 years (16 patients), 65-75years (4 patients) were represented in table no:1, figure: 2.

Table 1: Age distribution in patients

Age group	No. of Males	No. of Females	Total
18 -25yrs	22	8	30
25-35yrs	18	28	46
35-45yrs	19	19	38
45-55yrs	10	11	21
55-65yrs	4	12	16
65-75yrs	3	1	4

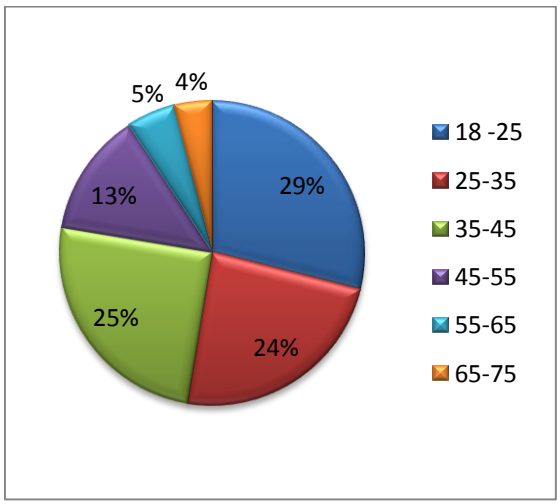


Figure: 2 Age distribution in patients

DISTRIBUTION OF PATIENTS BASED ON GENDER:-

A total distribution of 154 patients based on gender shows that female patients were 79 (51.3%) , and ,male patients were 75 (48.7%) , among which majority of them were female were represented in table no:2, figure:3.

Table: 2 Distribution of patients based on gender:-

Gender	Number	Percentage (%)
Male	75	48.7
Female	79	51.3
Total	154	100

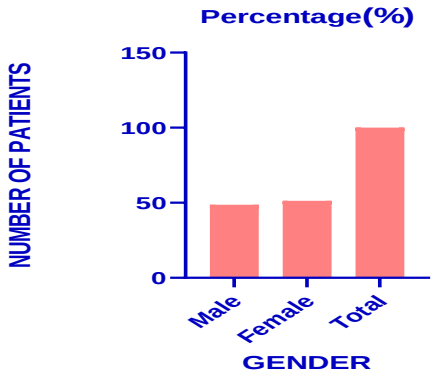


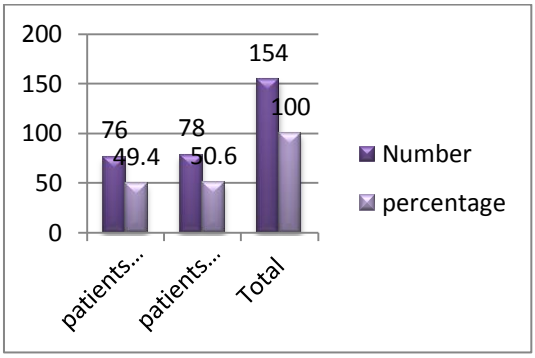
Figure no: 3 Distribution of patients based on gender.

DISTRIBUTION OF PATIENTS BASED ON EDUCATION LEVEL:-

Among all 154 patients in the psychiatry outpatient department, 76(49.4%) patients were educated and 78(50.6%) patients were uneducated were represented in table no: 3, figure no:4.

Table: 3 Distribution of patients based on education level:-

Patients	Number	Percentage (%)
Educated	76	49.4
Uneducated	78	50.6
Total	154	100



PATIENTS DISTRIBUTION BASED ON RESIDENCE:-

Out of 154 patients in the psychiatry outpatient department, 66(42.3%) patients were local residence of urban community and 89 (57.7%) patients were non local residence of rural community, represented in table no:4, figure no: 5.

Table: 4 Patients distribution based on residence

Patients	Number	Percentage (%)
In urban	66	42.3
In rural	89	57.7
Total	154	100

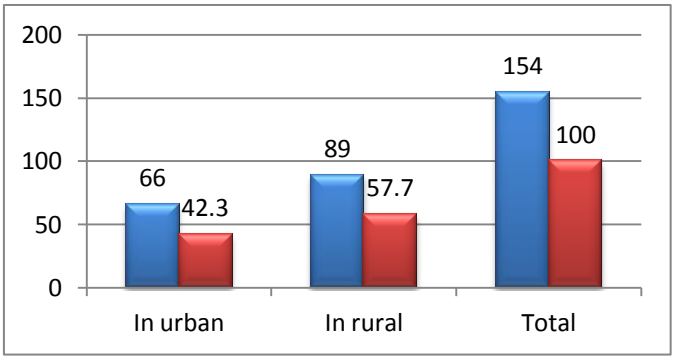


Figure no: 5 Distribution of patients based on residence.

DISTRIBUTION OF SYMPTOMS BASED ON GENDER:-

Among all the 154 patients 34 symptoms were observed and of these majority of the patients had the symptoms of decreased sleep ,self talking followed by anger ,anxiety ,hallucination ,irrelevant behaviour, shouting, decreased appetite, etc are depicted in the table no: 5,figure no:6

Table: 5 Distribution of symptoms based on gender

Symptoms	Male	Female
Decreased sleep	53	56
self talking	56	48
Hallucination	12	5
Anger	43	43
Anxiety	25	17
Shouting	16	18
Irrelevant behavior	47	41
Confusion	1	12
Decreased appetite	8	14
Self crying	10	14

Laughing	3	2
Loss of interest	8	1
Delusion	6	6
Anorexia	1	2
Suicidal thoughts	10	7
Giddiness	1	2
Weakness	1	2
Hostility	4	7
Irritability	3	4
Beating others	6	2
Fatigue	1	1
Decreased energy	2	8
Not taking food	2	1
Depression	2	19
Feeling alone	1	2
Restlessness	2	3
Headache	10	17
Unstable mood	2	9
Hearing sounds	2	4
Abnormal dreams	4	6
Palpitations	0	2
Breathlessness	0	1
Facial puffiness	1	2

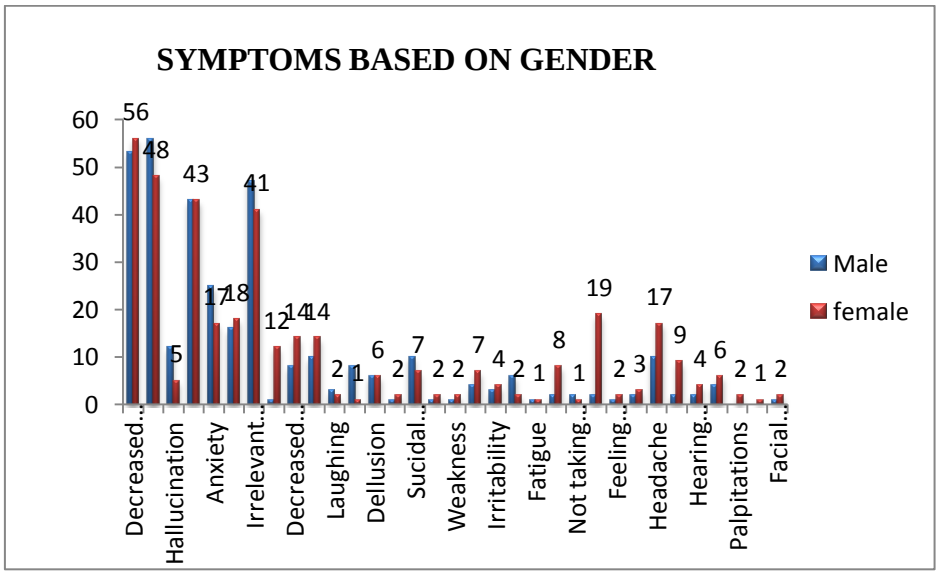


Figure: 6 Distribution of symptoms based on gender .

DURATION OF ILLNESS BASED ON PATIENTS GENDER:-

In bipolar disorder among 154 patients the distribution of patients based on duration of illness includes the majority of patients between 2mon-6years was 59 male and 65 female followed by 6years -11 years was 13 male and 10 female followed by 11 years to 16 years was 2 male and 3 female, and $\geq$ 16 years was 1 male and 1 female were represented in table no:6, figure no:7.

Table: 6 Duration of illness based on gender:-

Duration of illness	Male	Female
2mon - 6 years	59	65
6 yrs- 11 yrs	13	10
11 yrs- 16 yrs	2	3
≥16 yrs	1	1

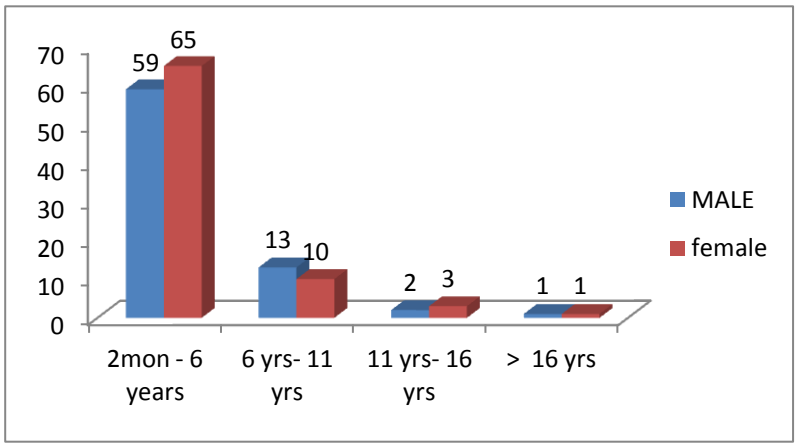


Figure: 7 Duration of illness based on gender

GENETIC INHERITANCE OF PATIENTS:-

A total of 154 patients in psychiatry outpatient department there is chance of genetic inheritance in 24(15.4%) patients and there is no chance of genetic inheritance in 130(84.4%0 patients were represented in table no: 7, figure no:8.

Table: 7 Genetic inheritance of patients:-

Genetic inheritance	Number n= (154)	Percentage (%)
yes	24	15.5
no	130	84.4

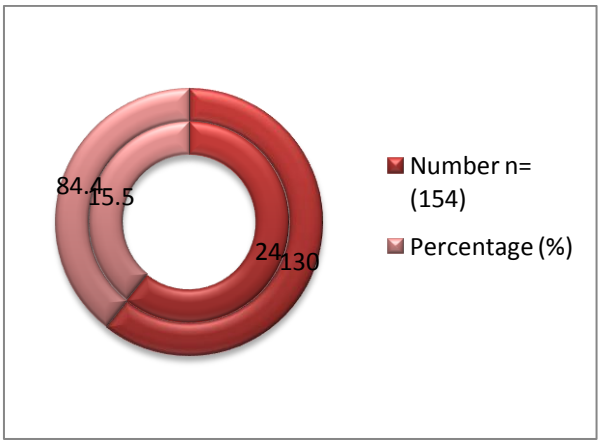


Figure: 8 Genetic inheritance of patients

TREATMENT ADHERENCE OF PATIENTS:-

Among 154 patients of psychiatry outpatient department 122 (79.2%) patients have good treatment adherence, whereas 32(20.7%) have poor adherence were represented in table no: 8,figure no:9.

Table: 8 Treatment adherence:-

Treatment adherence	Number n= (154)	Percentage (%)
Yes	122	79.2
No	32	20.7

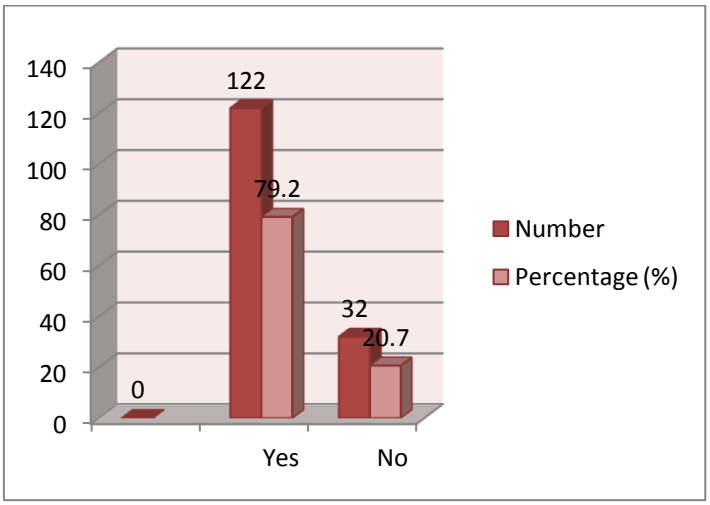


Figure no: 9 Treatment adherence of patients

DISTRIBUTION OF ANTIPSYCHOTIC DRUGS:-

A total of 154 patients and 287 drugs of class antipsychotics were enrolled in this study, of these majority of the patients received Olanzepine, followed by Risperidone, Quetiapine, Haloperidol, Clozapine, Aripiprazole and Chlorpromazine were shown in the table no: 9, figure 10.

Table no: 9 Distribution of Antipsychotics:-

Drugs	Male	Female
Clozapine	4	13
Olanzepine	65	69
Risperidone	38	32
Haloperidol	11	12
Aripiprazole	2	5
Chlorpromazine	2	0
Quetiapine	18	16

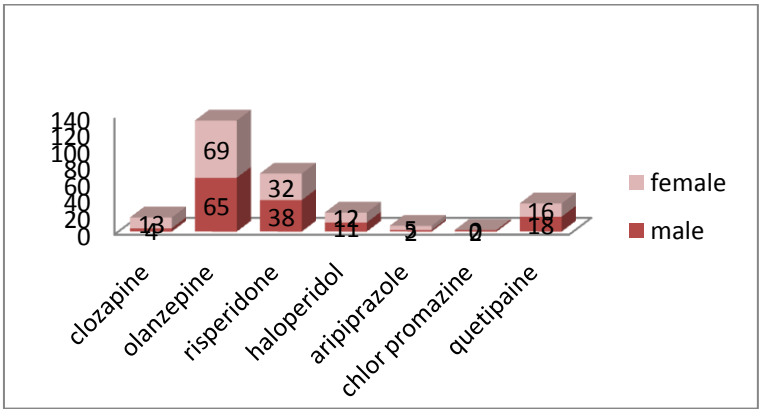


Figure no: 10 Distribution of Antipsychotics

DISTRIBUTION OF ANTIDEPRESSANTS:-

A total of 154 patients and 131 drugs of class Antidepressants were enrolled in this study, of these majority of the patients were receiving Amitryptiline followed by Escitalopram , Setraline and Buproprion were represented in the table no:10, figure no:11.

Table no: 10 Distribution of Antidepressants

Drugs	Male	Female
Escitalopram	18	22
setraline	17	15
Buproprion	1	2
Amitryptiline	19	37

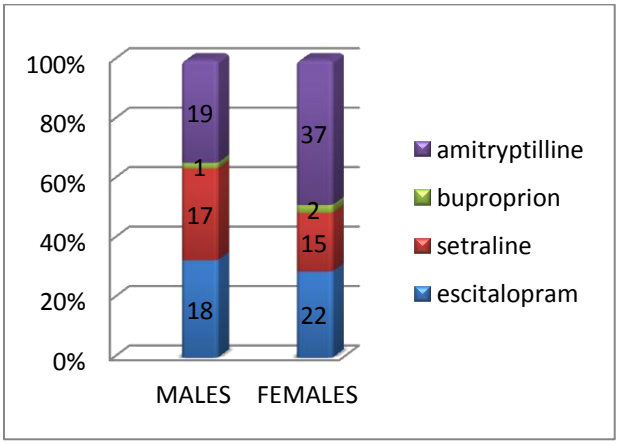


Figure: 11 Distribution of Antidepressants

Distribution of Mood Stabilizers:-

A total of 154 patients and 161 drugs of class Mood Stabilizers were enrolled in this study, of these majority of the patients received Sodium Valproate, followed by Lithium and Carbamazepine were depicted in the table no: 11,figure no: 12.

Table: 11 Distribution of Mood Stabilizers

Drugs	Male	Female
Lithium	30	22
Sodium valproate	52	42
Carbamazepine	10	5

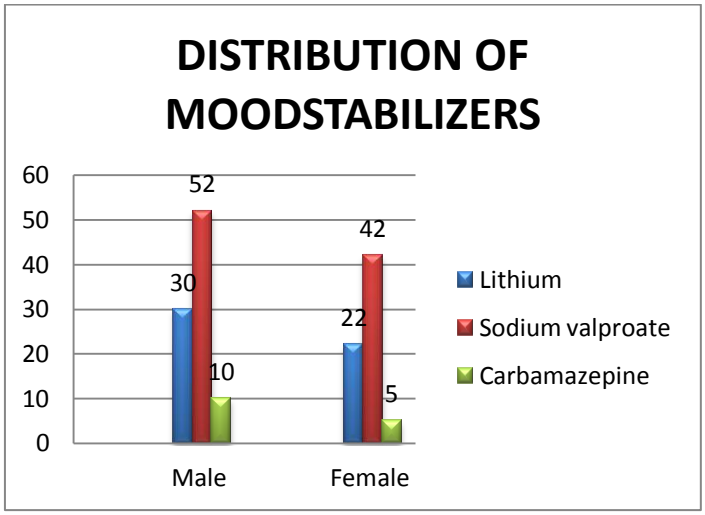


Figure: 12 Distribution of Mood Stabilizers

Adverse drug reaction	No. of Males	No. of Females	Total
Dry mouth	47	47	154
Confusion	35	14	154
Headache	40	32	154
Constipation	29	26	154
Sedation	26	24	154
Body weight gain	22	35	154
Increased appetite	11	15	154
Dizziness	20	21	154
Salivation	19	15	154
Anxiety	29	21	154
Decreased appetite	38	18	154
Fatigue	8	9	154
Malaise	2	2	154
Nervousness	7	1	154
Insomnia	3	1	154
Blurred vision	1	3	154
Somnolence	5	6	154
Restlessness	6	7	154
Parasthesia	3	2	154
Palpitation	2	0	154
Dyspepsia	2	2	154
Hallucination	15	7	154
Abnormal dreams	0	9	154
Seizures	0	2	154
Stiff neck	1	4	154
Nausea vomiting	0	3	154
Anorexia	0	2	154
Rash	1	4	154
Diarrhea	2	5	154

ADVERSE DRUG REACTIONS BASED ON GENDER:-

Among 154 patients of psychiatric outpatient department receiving Antipsychotics ,Anti depressants and Mood stabilizers 374 ADR's are reported in male patients and 337 ADR'sare reported in female patients were represented in table no:12, figure no:13 .

Table no: 12 Adverse drug reactions based on Gender

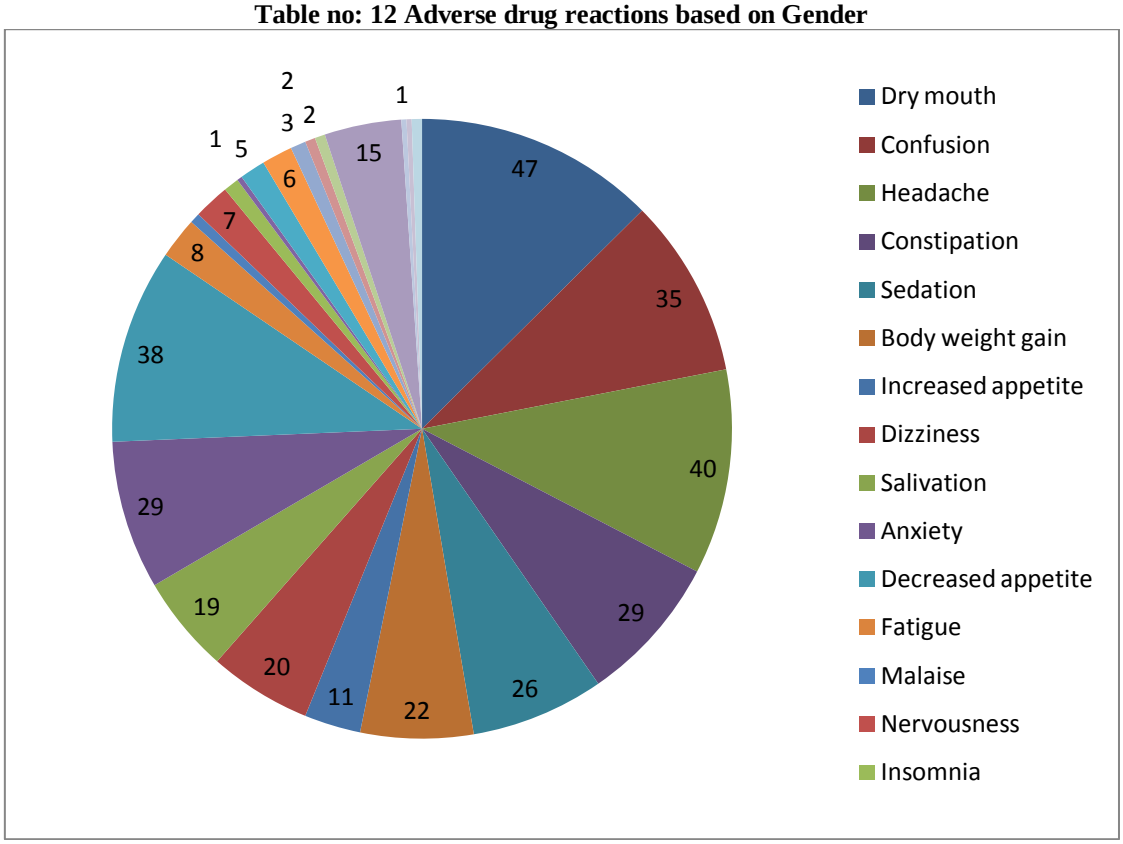


Figure: 13 Distribution of ADR's based on symptoms

SINGLE DRUG THERAPY:-

Among 154 patients receiving medication single drug therapy majority of the patients received olanzepine (111), followed by sodium valproate (93), risperidone (62), lithium (52), escitalopram (32), haloperidol (23) and carbamazepine (15) were represented in the table no :13 ,figure no:14 .

Table no: 13 Single drug therapy

Drugs prescribed	Prescribed in no. of patients (n= 154)	Percentage (%)
Risperidone	62	16
Haloperidol	23	6
Escitalopram	32	8
Lithium	52	13
Sodium valproate	93	24
Carbamazepine	15	4
Olanzepine	111	29
Total		100

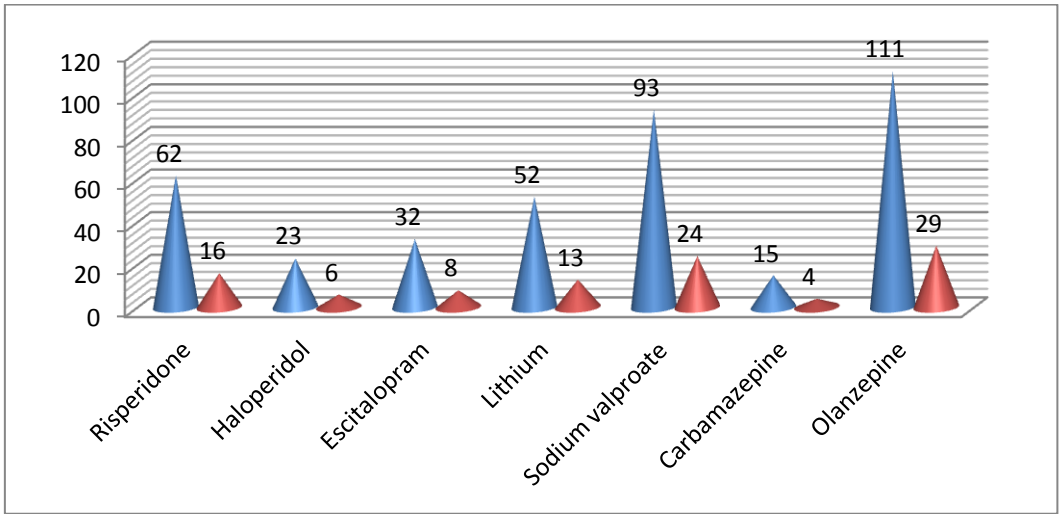


Figure no: 14 Single Drug Therapy

TWO DRUG COMBINATION THERAPY:-

A total of 154 patients 109 patients were receiving two drug therapy ,of these majorily used combination was olanzepine +risperidone 59 (54%), described in the table no: 14,figure no: 15

Table no: 14 Two drug combination therapy

DRUGS	Prescribed in no. of patients n=(154)	Percentage (%)
Olanzepine + Risperidone	**59**	**54**
Haloperidol + Olanzepine	**19**	**17**
Olanzepine + Escitalopram	**31**	**29**

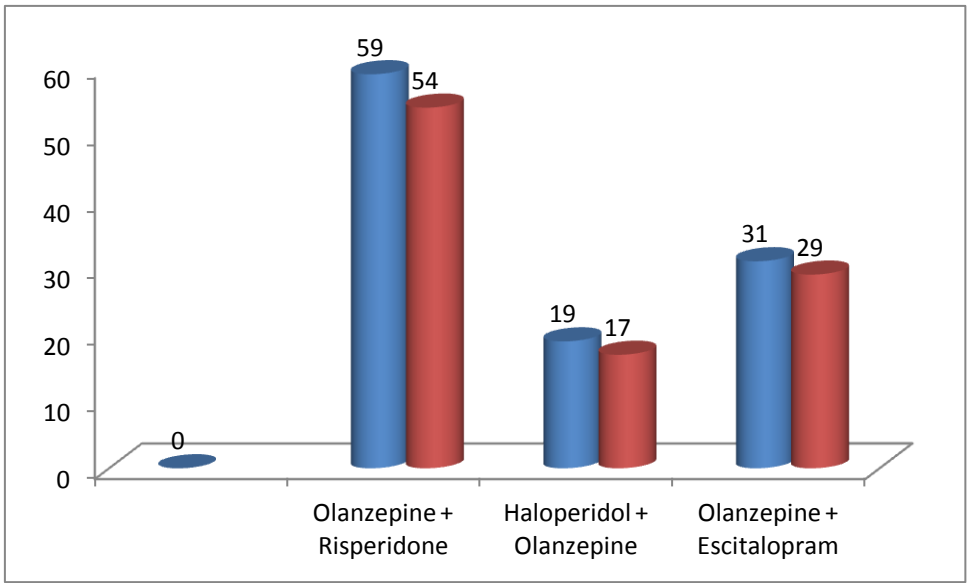


Figure no: 15 Two drug combination therapy

THREE DRUG COMBINATION THERAPY:-

Total of 154 patients 62 patients are receiving three drug combination therapy of these most majority used combination was Olanzepine +Risperidone +Quietiapine 20 (32%),are showed in table no: 15, figure no: 16.

Table: 15 Three drug combination therapy

DRUGS	Prescribed in no.of patients n=(154)	Percentage(%)
Olanzepine + Risperidone + Quietiapine	20	32
Haloperidol + Olanzepine + Risperidone	10	16
Olanzepine + Escitalopram + sertraline	16	26
Olanzepine + Queitiapine + Amitryptiline	16	26

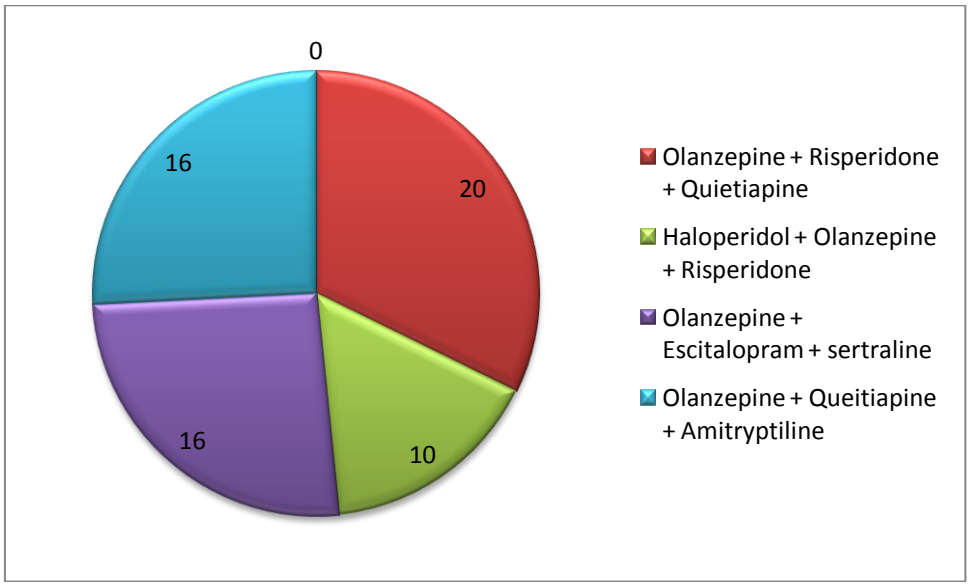


Figure no: 16 Three drug combination therapy

ASSESSMENT OF ADR's BY USING NARANJO's SCALE IN FEMALES:-

According to Naranjo's scale assessment of ADR's in female was found to be suspected as 18(4.54%) Definite ADR's, 218 (58.5%) Probable ADR's, 158(39.8%) Possible ADR's and 2(0.5%) Doubtful ADR's were depicted in the table no: 16, Figure no: 17.

Table: 16 Assessment of ADR's by using Naranjo's scale in females

Naranjo's score	Female patients	Percentage (%)
DEFINITE	18	4.54
PROBABALE	218	55.5
POSSIBLE	158	39.8
DOUBTFUL	2	0.5

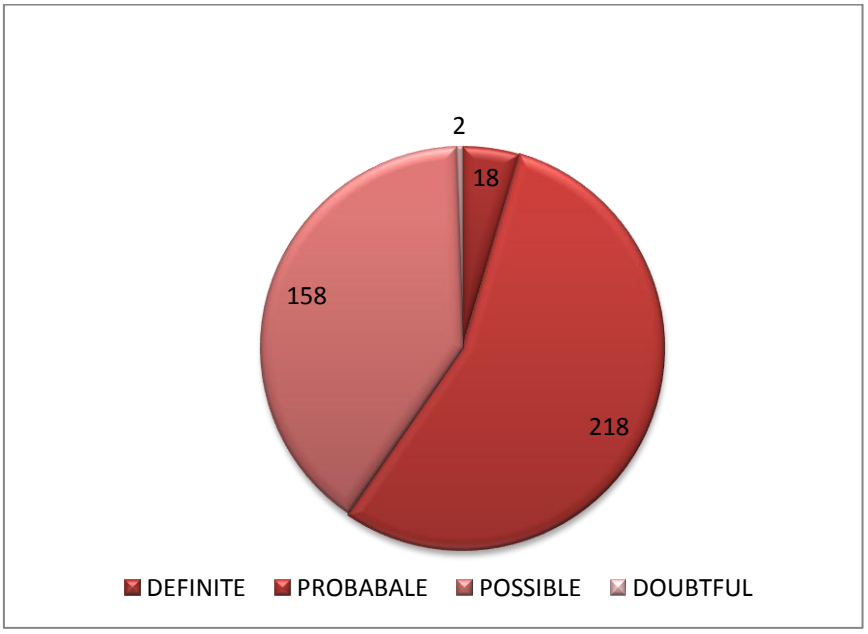


Figure: 17 Assessment of ADR's by using Naranjos's scale

ASSESSMENT OF ADR's BY USING NARANJOS SCALE IN MALE:-

According to Naranjo's scale assessment of ADR's in Males was found to be suspected as 7(1.87%) Definite ADR's, 182(48.6%) Probable ADR's, 176(47.5%) Possible ADR's and 9(2.4%) Doubtful ADR's were represented in table: 17, figure: 18.

Table: 17 Assessment of ADR's in Males

Naranjo's scale	Male patients	Percentage (%)
DEFINITE	7	1.87
PROBABLE	182	48.6
POSSIBLE	176	47.5
DOUBTFUL	9	2.4

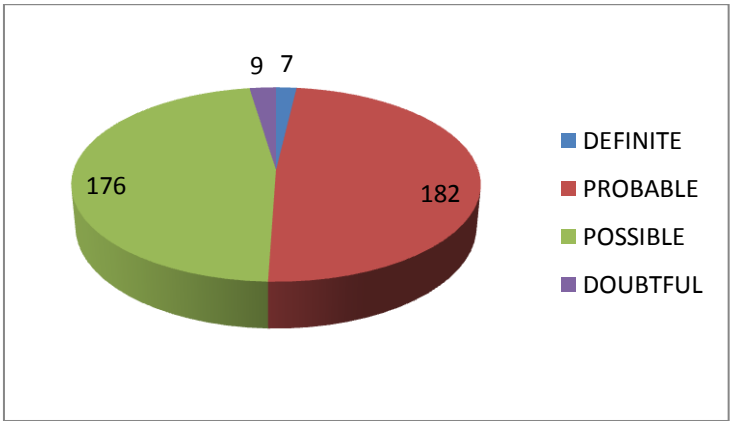


Figure no: 18 Assessment of ADR's in Males

IV. Discussion

The bipolar disorder can be defined as the psychological syndrome which is a severe and often relapsing mental disorder with abnormal mood and behaviour.

Our prospective observational study was conducted in 154 patients in psychiatric outpatient department shows that bipolar disorder occurs more in female 79 (51.3%) and relevantly less in males 75 (48.7%).

In this current study age distribution represents that majority of patients attended the psychiatric outpatient department were 25-35years 46(29.8%) followed by 35-45 years 38 (24.6%), 18-25years 30 (19.4%)

suffering from bipolar disorder. The reasons may be due to poly pharmacy, work pressure, stress. Our study includes the antipsychotics, antidepressants and mood stabilizer medications which are used for both bipolar mania and depression to elevate the mood based on the patient severity of illness.

Our study shows that 34 symptoms were observed among 154 patients in which majority of them had the symptoms of decreased sleep, anger, irrelevant behaviour, self talking, anxiety etc.

This study shows that if all 154 patients in psychiatric unit of outpatient department included in the study has 76(49.4%) educated and 78 (50.6%) are uneducated.

In our study bipolar patients have a duration of 2months -16 years, maximum no.of patients experience illness at starting of disease. At the initial of treatment of disease results the occurance of symptoms falls down and doesn't lead to chronic .The majority of patients of both the genders had the duration of illness of 2months - 6 years.

This current study shows 66 (42.3%) patients were local residence of urban community and relatively 89 (57.7%) were from non local residence of rural communities of total 154 patients.

In this present study the treatment adherence of patients was observed to be 122 (78.2%) and the prevalence of inheritance was 24(15.5%).

In our study A typical antipsychotics are prescribed a lot when compared to typical Antipsychotics depicts that the physicians give more importance in the patient health and quality of life. Of both the antipsychotics Atypical are preferred over Typical as they have less side effects and more effectiveness, low relapse rate. Regard to the antipsychotics, mood stabilizers are used for setting up the mood of patients following the antidepressants of class SSRI's and TCA due to lesser side effects and better tolerability.

In our study, olanzapine 134(87.09%) the most commonly used Anti psychotic drugs followed by risperidone 60 (38.9%), Haloperidol 23 (14.9%). The reason for this as olanzapine reduces the psychotic symptoms, reduces hospitalization, minimizes side effects and also reduces overall medication costs.

Atypical antipsychotics are commonly prescribed medication owing to their better tolerability, low relapse rate, more effectiveness. Amitriptyline is the mostly used antidepressant drug having better efficacy, earlier onset of action, more effectiveness, definite superiority in the treatment of bipolar disorder.

Atypical antipsychotic with the combination of mood stabilizers and Antidepressants is preferred because of control over the mood,psychotropic symptoms and to control the progression of the disorder .our study showed the prescribing pattern of drug combination like Olanzapine+Risperidone,Haloperidol+Olanzapine, Olanzapine+Escitalopram .

Sodium valproate was commonly prescribed mood stabilizer in regard to lithium and carbamazepine which are used to elevate the mood .

In our study the most commonly used Antidepressants was Amitriptyline (56) , following escitalopram (40) , sertraline (32), bupropion (3) are SSRI's. Our study among 154 patients a total of 411 adverse drug reactions were developed regarding the use of Antipsychotics, Antidepressants and Mood stabilizer medications in both male and female patients ,where as a count of 374 adverse drug reactions were reported in male and 337 adverse drug reactions were reported in female patients.

In the current study the adverse drug reactions were more in male compared to female.The difference in prevalence of ADR's in psychotropic medications may be due to age, hormonal, psychological factors and socio-economic factors etc.

In the present study we conclude that majority of the patients have the ADR of confusion, followed by weight gain , constipation, anxiety, anger, dizziness, etc may be due to stress, sensitivity to the effect if psychiatric medications and susceptible to the adverse drug reactions. Of all 411 adverse drug reactions identified in our study, the most common were probable ADR's 218 (55.5%), leading by possible ADR's 158 (39.8%), definite ADR's18 (4.84%) and doubtful ADR's 2 (0.5%).As the bipolar disorder is the longterm illness the use of drugs for prolonged time cause adverse drug reactions which may be due to non -compliance Adverse drug reactions are most common in all of the prescriptions.

Moon drug therapy, two drug therapy and three drug therapies are used to get the better outcomes of the disease in bipolar patients where as four drug combination and five drugs combination are not used in any of the154 prescriptions.

In our study it is clear that single drug therapy of Olanzapine 111(29%) was most prescribed followed by Risperidone(16%), Escitalopram (8%), Sodium Valproate (24%), Lithium (13%), Haloperidol (6%), Carbamazepine (4%) where as the two drug combination therapy and three drug combination were used less frequent .Among the adverse drug drymouth is the mostly reported ADR leading by headache, confusion ,sedation etc

The management of adverse drug reactions like drymouth, weight gain, confusion, headache other drugs like Diazepam, THP, Propranolol, Pantop and other Anticholinergics were added to the prescription.

In our present prospective observational study the assessment of suspected adverse drug reactions was done by using Naranjo's scale revealed that most of the adverse drug reactions are probable 218 (55.5%) and the management of the ADR's was done.

V. Conclusion

Clinical profile and Drug utilization evaluation helps in altering trends overtime. DUE has become a popular tool to be used in the evaluation of health systems. Among most of the mental illness bipolar disorder is one of the toughest to subdue.

In this study we also conclude that females are more prone to cause bipolar disease than compare to males.

Of all the medications mood stabilizers like Sodium Valproate & lithium and anti psychotics like Olanzapine are majorly used along with the combination of Escitalopram, Sertraline, Amitriptyline.

Out of all the prescribed medication Sodium Valproate is the mostly used mood stabilizer and Escitalopram which is SSRI anti depressant are prescribed because of less side effects, better tolerability, appreciative complementary risk –benefit ratio than other drugs; and also have favourable pharmacokinetic profile with declined risk of drug –drug interactions.

The setting of active Pharmacovigilence helpful to prevent possible ADR`s and help in monitoring the ADR`s and improving the quality of life with patient care by providing rational use of drugs.

Though Olanzapine is preferred antipsychotic it has low relapse rate and more effectiveness in decreasing the psychotic symptoms and control the mood, but the antipsychotics show the ADR`s like weight gain similarly the anti depressants show the ADR vomiting and the mood stabilizers show ADR dry mouth .

The assessment of suspected ADR`s done by using Naranjo`s scale, revealed the majority of ADR`s are probable.

All the drugs were prescribed by generic name, this indicates the good prescription habit. Prescribing medicines by official generic names avoids the confusion and makes the drug therapy rational and cheaper. In our study government policy was totally followed and all drugs were from state essential drug list. This is an extremely advantageous policy for common people as it ensures health compliance for all without implicating financial burden on patients.

Clinical pharmacist plays an active part in the identifying, monitoring, and reporting of ADR's.

This helps in early detection, prevention, and management of ADR's which reduces the treatment cost and enhance medication adherence pattern. Under - reporting due to lack of awareness both at the level of health care professionals and patients leads to serious complications so that should be addressed immediately .

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