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Teratogenic risk awareness and practice of contraceptive use among reproductive age women with bipolar disorder attending Amanuel Specialized Mental Hospital, facility based cross sectional study

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Abstract

Background

Treatment of bipolar disorder in female patients pauses great difficulty because medications that are being used have risk of causing congenital malformations and neurodevelopmental problems in babies born to mothers who took the drugs during their pregnancy and also women with bipolar disorder have higher risk of untended pregnancies and birth related complications than the general population. So female patients who are in the reproductive age group should be aware of these risks and should be able to take necessary precautions which include pregnancy planning, effective contraceptive use and folate supplementation.

Objective

To assess awareness of teratogenic risk and practice of contraceptive use among reproductive age women with bipolar disorder

Methods A hospital-based cross-sectional quantitative study was conducted at Amanuel Specialized mental Hospital. Samples of 384 consecutive outpatients with bipolar disorder diagnosis were enrolled. Data was collected using structured questionnaire which was administered by psychiatry nurses. Data was analyzed using the Statistical Package for the Social Sciences (SPSS), Version - 21.

Results – 384 participants who had follow up at Amanuel specialized mental hospital outpatient clinic participated in the study. About 40% of participants reported that they have awareness about teratogenic risk of mood stabilizer treatment.

38.28% reported current use of contraceptive methods. Among the participants who were taking mood stabilizers 223(60.6) did not use contraceptive

Conclusions -In this study, the majority of women with bipolar disorder did not have awareness about teratogenic risk and majority of them reported that they were not using contraceptive methods. Psychoeducation about teratogenic risk and the need for contraceptive use for women with bipolar disorder attending psychiatric outpatient clinic should be strengthened.

Key words: bipolar disorder, women, contraceptive, teratogen, Amanuel specialized mental hospital, Ethiopia

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Acronyms

AED – Antiepileptic drugs

AMSH – Amanuel specialized mental hospital

BD - Bipolar disorder

OC – Oral contraceptives

DSM 5 = Diagnostic and statistical manual of mental disorders fifth edition

FDA – Food and Drug Administration

Mg – milligrams

PI – principal investigator

SPSS = Statistical package for the social sciences

WBD - Women with bipolar disorder

WWE – Women with epilepsy

1 Introduction

Bipolar disorder is a chronic mood disorder characterized by at least one hypomanic, manic, or mixed episode. Mixed episodes are characterized by a combination of depressive and manic or hypomanic symptoms. Although a small percentage of people have exclusively manic episodes, the majority of bipolar disorder patients have experiences of both polarities. Manias are more common in men, while depression is more common in women.(1)

Given the female majority and the young age at which bipolar disorder manifests itself (17.5 years) (2), A large number of patients are women of childbearing age.
Managing bipolar disorder in this age group is complicated.(3) Treatments usually entails use of medications that are not only teratogenic or unsafe to the fetus such as the anticonvulsant mood stabilizers or lithium but may also interfere with the clearance of oral contraceptives.(14)
Lithium is one of the mainstay treatments for bipolar disorder. It is associated with congenital malformation specifically cardiovascular anomaly (Ebstein's anomaly) (4)

Anticonvulsants have been used to treat psychiatric disorders for over fifty years, with bipolar affective disorder being one of the most common.(5)
Anticonvulsants specifically carbamazepine and sodium valproate emerged as an alternative mood stabilizers to treat cases where Lithium is not effective or tolerated. (6)

Studies, mostly in women with epilepsy indicate that both medications independently increase the risk of major congenital abnormalities when administered in the first trimester. This effect is not thought to be related to maternal seizure activity.(5)

When compared to the general population, AEDs have been linked to a two to three fold increase in significant abnormalities in infants exposed to them in utero. Investigators were also alerted to the likelihood of longer-term negative consequences after early reports of mild aberrations and cognitive impairment. (7)

The teratogenic risk linked with divalproex and carbamazepine during pregnancy has also been confirmed by cohort studies in a variety of patient demographics.(8)
FDA has also categorized carbamazepine and valproate as pregnancy category D and X respectively.(9)(D implies positive evidence of human fetal risk, X- confirmed human fetal risk

Valproate is currently widely regarded as the antiepileptic drug with the highest teratogenic potential. (10)**.** It is linked to teratogenic risks such as neural tube abnormalities (spina bifida) and other birth problems. When compared to other drugs like carbamazepine (2.4%) and lamotrigine (2.7%), there was a 6.3 % increase in craniofacial defects, cardiac anomalies, microcephaly, and growth retardation. (10)

The rate of significant congenital abnormalities in newborns delivered to mothers using valproate monotherapy throughout pregnancy has been estimated to be 11 percent, compared to 3 percent in women without epilepsy, according to two significant meta-analyses of data from trials around the world.(11)

Furthermore, babies exposed to valproate preparations in gestation have a relatively significant risk of neurodevelopmental abnormalities (between 30 and 40 in every 100) including autistic spectrum disorders and lower intelligence)(12)

Generally antiepileptic polytherapy and higher doses are associated with an increased risk of teratogenicity. (10) Valproate doses greater than or equal to 1000mgs is generally associatedwith a broader range of teratogenic risk (21.9%) than smaller doses (2.5%). (10)

Recommendations are being given to restrict the use of these drugs and if restriction is not possible it is important to conduct clinical discussion which includes teratogenic risk, pregnancy planning, contraceptive advice and use of high dose folic acid in women who are in reproductive age group. (10, 12, 13)

Many women of childbearing age are unaware of the teratogenic danger of valproate, and are therefore unaware of the necessity for contraception or prophylactic folate. (13)

In addition when a woman is in manic state, she is likely to be sexually disinhibited which puts her at risk for unintended pregnancy.(12) So unintended pregnancies occur at a higher rate in these women than in the general population which is 40% to 50% , (14) which increases the likely hood of the fetus being exposed to the teratogenic antiepileptic drugs.
Previous literatures point out that there is lack of understanding of teratogenic risks and low prevalence of contraceptive usage among WBD. It is indicated that women with mental illnesses have difficulty in using family planning services due to low levels of awareness, high levels of stigma and various disease related factors(26) which is an implication for the need for continuous psychoeducation and support practice in the management of BD.(9)
When discussing treatment strategies for female patients planning pregnancy, the anatomical and neurobehavioral teratogenic risks for exposed fetuses need to be weighed against the hazards of discontinuing effective bipolar treatment. (15)

In addition, if BD is not adequately treated there will be worse outcome due to the exposure of the fetus to the mother's illness as well as to the potential teratogenicity of the drug. (15)
In many clinical situations stopping bipolar treatment is not a practical choice necessitating continued treatment and a detailed understanding of the dangers associated with each bipolar medication. (15, 16)

2 Literature review

There are some studies done in different countries to assess the teratogenic risk awareness and practice of contraceptive use among women with BD and epilepsy.

When taking a possibly teratogenic AED, 30/115(26%) of women had a recorded contraceptive technique, according to a study conducted at the University of Colorado Hospital in the United States. 15(50%) of the 30 patients were using an oral combined hormonal contraceptive, 3(10%) were using a progestin-only pill or implant, 5(17%) were using depot medroxy progesterone acetate, and 7(23%) were using an intrauterine device (either levonorgestrel or copper). For the patients on the combined hormonal contraceptive, 13/15 women had a potential for a drug–drug interaction with their AEDs as well as 1 out of 3 subjects that were on the progestin-only pill or implant.

Two women not taking the contraception became pregnant while on the category D or X AED. One had a miscarriage, and one received an abortion after learning of the pregnancy. After the events, one of the patients was immediately placed on a contraception plan.

In the study it was indicated that less than 7% of subjects received counseling on a contraception plan, and 18% of subjects received counseling on a pregnancy plan. For the 36 women who were prescribed the AED for the first time or who had previously tried the AED and were resumed in the year of interest, 4 received contraception counseling (11%) and 8 received pregnancy plan (22%). (17)

In a cross sectional study that was conducted in Colombia university, USA in 2009 to assess demographic characteristics, current AED use and knowledge of AED interaction with OCs and teratogenicity among epileptic reproductive age women, the mean age was 31.7 years (SD 7.8), with 26% aged 18 to 25, 36.4% aged 26 to 35, and 37% aged 36 to 44.

The 148 women who completed the study questionnaires reported taking 154 Category C AEDs and 50 Category D AEDs. Six women (4%) reported that they were not on AED therapy and two of these women were pregnant, 89 (60%) were taking one AED, 44 (30%) reported taking two AEDs, and 9 women reported taking three AEDs.

In the study the most common response was that women did not know if their AED affected fetal development. 45% of women taking Category C AEDs and 40% of women taking Category D AEDs did not know if their AED affected fetal development.

In this study, some women indicated that there was ‘‘no effect” of a Category D AED or even a ‘‘good effect” on a developing fetus. Ten (6%) women reported their AED had an unknown effect on fetal development and there was no one who reported the effects of any Category D AED as unknown. (18)

In a survey of 2788 women aged 16 to 50 with epilepsy conducted in 2016 by the charities Epilepsy Action, Epilepsy Society, and Young Epilepsy in collaboration with the Medicines and Healthcare Products Regulatory Agency (MHRA), it was discovered that one in five (20%) women currently taking sodium valproate were unaware that it could harm the development and physical health of their baby. also 27% of the respondents reported that they had not discussed the risks involved in pregnancy with a health professional. (19)

In an internet based survey that aimed to assess the level of pregnancy related knowledge of women with epilepsy and their informational needs concerning pregnancy and childbirth issues in German speaking countries, 179 patients 19 to 41 years of age participated and 60% had received information about pregnancy and delivery, 38% of WWE taking enzyme inducing antiepileptic were unaware of the interaction with OC and 41% of the participants taking valproate reported being unaware of its teratogenicity. (20)

In a study conducted in Ireland in 2016, researchers used a retrospective chart review and a semi structured interview to evaluate clinical note documentation of valproate prescription and to assess the level of knowledge among women of reproductive age group about valproate associated adverse effects including teratogenesis. During the interview, 33.3 percent (n =14) of participants indicated that they were aware of the risk of valproate, with only 19.0 percent (n = 8) being aware of specific teratogenic risks, the need for contraception, and a pregnancy test before starting valproate, and 16.7 percent (n = 8) reported being aware of the need for folic acid while taking valproate. In this study, with the exception of one, all of these participants said they

got this information from their treating consultant psychiatrist. 18 (42.9%) individuals had either documented data in their clinical notes or reported that their mental health team had advised them on at least some of the risks of valproate for women in the reproductive age group. (21)

In a study conducted in Turkey to examine impulsivity, contraception use, and reproductive characteristics in euthymic WBD in comparison with healthy women, the mean age of individuals in the WBD group was 31.5±7.1 years, while the control group was 36.05.4 years (p =0.000. The WBD group had considerably higher unemployment rates (p = 0.016).
In this study WBD had a higher overall rate of contraceptive use (96.6%); however they tended to favor "traditional" methods (i.e. withdrawal and calendar). WBD had a much higher rate of unintended pregnancies than women without bipolar illness (49.52 percent vs. 15.04 percent respectively) (22)

In cross-sectional survey done in Brazil in 2009, of 136 women with bipolar disorder, prevalence of contraception use was 58.8%.The study showed that use of any contraceptive method was more frequent in those who are married or living with a partner (OR=2.87, 95%CI 1.38–6.00), younger age (OR=2.10, 95%CI 1.05–4.23) and a linear-to-linear association emerged with number of pregnancies (χ=4.88, p=0.03).Use of contraceptive was unrelated to income (F=0.762, p=0.385) or years of education (F=0.002, p=0.962). No associations were found with symptoms or illness severity. The study also showed that use of lithium and anticonvulsant mood stabilizers was unrelated to use of contraception, and a considerable fraction of patients on these medications did not use any method (39.6% and 41%, respectively). So this study showed that Women diagnosed with bipolar disorder and treated in a tertiary facility use contraceptive methods suboptimally. (23)

In a study done in Addis Ababa Ethiopia, out of 422 female participants with severe mental illness about 68% reported that they have heard about family planning, 38.6% of participants reported use of contraceptives and 88% of participants reported that they had unintended pregnancies. Fear of drug interaction was the most reported reason not to use contraceptive methods.(24)

3 Statement of the problem

Given the hazards of anticonvulsant drug usage during pregnancy, it is critical for WBD to be aware of these hazards and to practice preventive measures like consistent contraceptive use and folic acid supplementation.

Research on contraceptive use in patients with mood disorders is very limited (25).

However previous researches done have demonstrated low rates of teratogenic risk awareness and contraceptive use practice (19, 21, 22, 23))

As to my knowledge there are no similar studies that were done in Amanuel specialized mental hospital which is the only tertiary hospital in the country where large number of cases are seen.

Knowing the level of awareness of teratogenic risk and contraceptive practice of the patients might indirectly allow to assess the quality of practice that is being given and to assess needs of patients and to plan for a solution.

4 Significance of the study

The significance of the study will be:

1. To provide a data on the level of teratogenic risk awareness and contraceptive use practice of women with bipolar disorder in Amanuel Specialized Mental Hospital
2. To serve as a reference for future similar studies

5 Research question

What is the level of awareness of teratogenic risk and contraceptive use among women with bipolar disorder?

6 Objectives

6.1 General objective

To assess awareness of teratogenic risk and practice of contraceptive use among reproductive age women with bipolar disorder

6.2 Specific objectives

1) To assess awareness of teratogenic risk in patients with bipolar disorder
2) To assess practice of contraceptive use among reproductive age women with bipolar disorder
3) To assess factors that determined teratogenic risk awareness and contraceptive use

7 Methods

7.1 Study Area and Setting

Amanuel specialized mental hospital is the main treatment center in Ethiopia for patients with mental illnesses and it is located in the Addis Ababa around Mesalemia area. It is the first psychiatric hospital in Ethiopia and was established by Italian invaders while the country was occupied by Italy from 1935-1940 for general purpose and it was transformed to a specialized psychiatric hospital in 1948.

The hospital has a capacity of 261 beds with a total number of 953 employees, among which over 500 are clinical staffs.

The hospital has an inpatient, outpatient, and emergency services and also gives forensic evaluation and treatment for substance use related problems. Currently it is the only tertiary hospital where inpatient and outpatient management of severe psychiatric cases is provided.

7.2 Study design

Hospital based cross sectional study

7.3 Study period

Data was collected prospectively from July to September, 2021

7.4 Study population

All female patients from 18-49 years old and who were diagnosed to have bipolar disorder and who visited the hospital for their regular follow up during the data collection period

7.5 Source population

All female patients of age 18-49 years old and who were diagnosed to have bipolar disorder

7.6 Inclusion criteria

Female Patients that are between the ages of 18 and 49 with established diagnosis of bipolar disorder according to DSM-5 and who are able to give consent

1) Bipolar I disorder
2) Bipolar II disorder
3) Cyclothymic disorder
4) Substance/medication-induced bipolar and related disorder
5) Bipolar and related disorder due to another medical condition
6) Other specified bipolar and related disorder
7) Unspecified bipolar and related disorder

Those who have received treatment at ASMH outpatient psychiatry clinic with minimum of one prescription fill before their current follow up visit

7.7 Exclusion criteria

1) Female patients who were not willing to participate in the study
2) Acutely unwell patients requiring emergency treatment
3) Patients with cognitive impairment who were unable to communicate
4) Female who had hysterectomy

7.8 Sample size

A single population proportion sample size determination formula was used based on confidence interval approach. There was no determined proportion from previous similar study. Hence, p was taken to be 50%, with 95% confidence interval ($Z_{\alpha/2}$=1.96) and 5% margin of error (d= 0.05).

$$n = \frac{(Z_{\alpha/2})^2 xp(1-p)}{d^2} \qquad n = \frac{(1.96)^2 x0.5(1-0.5)}{(0.05)^2} \qquad n=384$$

Where: n= is the minimum sample size required

p = is an estimate of the prevalence rate for the population (50%).

1-p= is the degree precision, 1-0.5 = 0.5

d =is the margin of error tolerated = 0.05

z =is the standard normal value = 1.96 at 95% confidence level.

7.9 Sampling procedure

Consecutive female patients with a diagnosis of bipolar disorder between the ages of 18 and 49 were included until the calculated sample size was reached in the study period

7.10 Data collection procedures

A structured Questionnaire was used to collect data. Data was collected by interviewing the study participants when they appeared in the hospital for their regular follow up visit. It was conducted in Amharic language. The questionnaire has information including socio-demographic profile (age, marital status, educational background, work, and address), type of medication, duration of treatment, folic acid supplementation, information about awareness of teratogenic risk and contraceptive use, any pregnancy test done before initiation of treatment, any pregnancies while taking the medication.

The Questionnaire was administered by 4 psychiatry nurses. Data quality was controlled by training data collectors on the contents of the Questionnaire and by supervision during data collection process. The collected data was checked for completeness then entered to SPSS

version 21 for further analysis and summary. Descriptive statistics were calculated for the variables. In bi-variate analysis, crude odds ratio and confidence intervals were calculated and used to select candidate variables for multivariate analysis using a significance level of $p<0.05$. Multivariable logistic regression was used to obtain adjusted odds ratios and corresponding 95% confidence interval (CIs). The strength of association was interpreted using the adjusted odds ratio and 95% CI.

8 Study variables

Independent variables: All the listed Sociodemographic and Clinical factors.

Dependent variables: teratogenic risk awareness, contraceptive use

9 Operational definitions

Teratogenic risk awareness – in a patient who is taking mood stabilizers, know that it could harm the development and physical health of their unborn child if they become pregnant.

Consistent contraceptive use- use of contraceptive throughout the treatment period with mood stabilizer.

Mood stabilizers – refers to medications used to treat mood disorders characterized by intense and sustained mood shifts such as BD and Schizoaffective disorder

10 Ethical considerations

Ethical clearance was obtained from Addis Ababa University, college of health sciences, psychiatry department Research Ethical Review Committee and Amanuel specialized mental hospital before starting the study. Written consent was sought from patients. The information found from this study was kept anonymous and was used for study purpose. Patients were given appropriate psychoeducation about teratogenic risk, importance of pregnancy planning and contraceptive use and some of patients were also provided with papers to read containing information about teratogenic risks associated with mood stabilizers and were advised to have

further discussion with their treating professionals. In the process of doing this research if any risk to the patient such as mismanagement of the illness, non-adherence issues or risk to suicide etc... were identified proper measures such as communication with the treating physician, consultation to a senior physician, psychoeducation to the patient and if necessary, referrals for admission were undertaken.

11 Results

Sociodemographic Characteristics of participants

In the current study, a total of 384 women with age ranging from 18years to 49 years ,with bipolar disorder diagnosis and who were on follow-up at AMSH participated. The majority (43.8%) of them were less than30 years old with a mean (standard deviation) age of 32.03± 6.319 and a median age of 32 years.

130(33.9%) of the participants had attended secondary education and 128 (33.4%) of participants had an elementary or below educational level.

Majority, 180(46.9%) of the participants were single, 99(25.8%) were married, 105(27.3) were divorced or widowed.

The results of these and the rest of sociodemographic factors are summarized in detail in the following table (Table 1).

Table 1: Sociodemographic & clinical characteristics of Participants, 2021

Characteristics	Number (%)
Age in years	
<30	168(43.8)
30- 39	164(42.7)
40- 49	52(13.5)
Marital status	
Married	99(25.8)
Single	180(46.9)
Divorced or Widowed	105(27.3)

Number of children	
No child	190(49.5)
1 to 2 children	171(44.5)
More than 2 children	23(6)
Educational status	
Not educated	36(9.4)
Primary education	92((24)
Secondary education	130(33.9)
Post secondary education	126(32.8)
Occupation	
Housewife	65(16.9)
Student	36(9.4)
Self employed	100(26)
government employee	58(15.1)
Jobless	98(25.5)
Address	
Urban	301(78.4)
Rural	83(21.6)
Type of psychotropic medication	
Mood stabilizer	369(95.83)
Antidepressant	7(1.8)
Antipsychotic	117(30.5)
Duration of treatment with mood stabilizers	

Less than 6 months	55(14.3)
More than 6 months	314(81.8)
Psycho education received from health professional about teratogenic risk	
No	236(61.5)
yes	148(38.5)
Taking folic acid	
Yes	3(0.8)
No	381(99.2)
Pregnancy test done before Rx initiation	
Yes	134(34.9)
No	151(39.3)
Don't remember	99(25.8)

Clinical Characteristics of participants

95.83 %(n=369) of the participants were taking one or combination of mood stabilizers. Sodium valproate was the most frequently prescribed mood stabilizer (n= 271). 25.3% of the participants were taking carbamazepine or lithium and 4.2% of participants were not on mood stabilizers.

From those participants who were taking mood stabilizer treatment,314(81.8%) reported that they took their medication (mood stabilizer) for more than 6 months before their recent visit to the hospital.

38.5 %(n= 148) of the participants reported that they have received psychoeducation about teratogenic risk of the treatment and the need for contraceptive use during their follow up visits. 236(61.5%) of the participants reported that they didn't receive or don't remember whether they received psychoeducation or not.

134(34.9) of the participants reported that pregnancy test was done before initiation of treatment. 151(39.3) of them reported pregnancy test was not done before treatment initiation and 99(25.8%) reported that they don't remember whether pregnancy test was done or not before treatment initiation.

32 patients reported history of being pregnant while they were taking mood stabilizer.

Teratogenic risk awareness and contraceptive use practice of the participants

From the 384 participants about 39.6% reported that they are aware that the medications that they are taking might harm their baby if they become pregnanat.135(35.2%) of the participants reported that they got the information about teratogenicity from health care professional, 8(2.1) from friends and the rest reported that they got the information from multiple sources. 38.28 %(147) of the participants reported that they use contraceptive and of these 113 reported they use contraceptives continuously during their medication use and 36 participants reported to use contraceptives sometimes.

The most frequently used method of contraception were implants (48.9%; n = 72) and injectables (42.17%; n = 62). On the other hand, (4%; n = 6) and (3.4%; n = 5) of the women were using oral contraceptive pills and condoms respectively.

From those who are on mood stabilizers 223(60.6%) reported that they were not using contraceptive method.

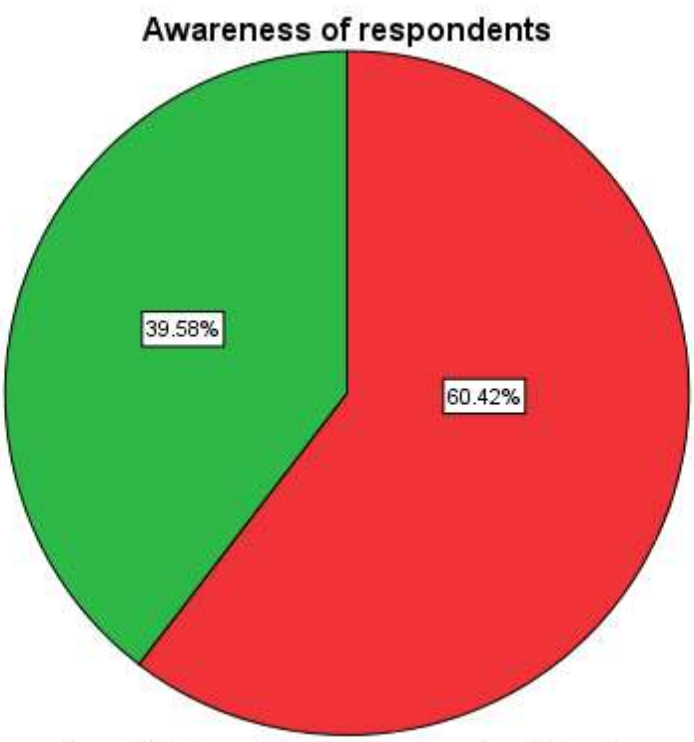

figure1 Teratogenic risk awareness of participants

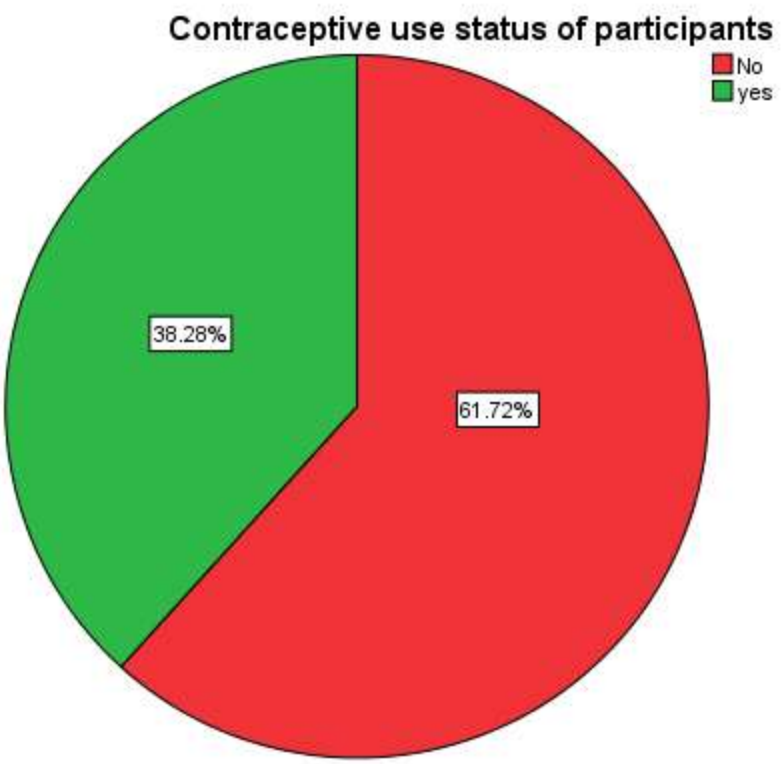

figure 2 Contraceptive use practice of participants

Contraceptive use and reproductive characteristics of the respondents

Variables	N (%)
Contraceptive use	
yes	147(38.3)
no	237(61.7)
Type of contraceptive	
Implants	72(48.9)
Injectables	62(42.17)
OCP	6(4)
Condom	5(3.4)
Current pregnancy	
yes	1(0.3)
no	383(99.7)
Number of pregnancies so far	
one	55(14.3)
two	59(15.3)
More than 2	79(20.6)
Previous pregnancy complications	
once	25(6.5)
twice	1(0.3)
Pregnancy while taking mood stabilizer	
yes	32(8.3)
no	352(91.5)

Table 2: contraceptive use and reproductive characteristics of participants

Factors associated with Teratogenic risk awareness and contraceptive use of the participants

On univariate analysis, age, marital status, number of children and mood stabilizer treatment were found to have statistically significant association with teratogenic risk awareness but address, educational level and psychoeducation received did not have statistically significant association with teratogenic risk awareness of the participants.

On multivariate analysis mood stabilizer treatment was associated with teratogenic risk awareness (p = 0.042). Women who were taking carbamazepine or lithium were less likely to be aware of the teratogenic risk.(AOR= 0.65, 95% CI: 0.38,1.12).

Similarly on univariate analysis mood stabilizer treatment, Age, address, marital status, number of children, educational level, psycho education received has statistically significant association with contraceptive use practice but educational level and mood stabilizer treatment were not found to be statistically significant predictors of contraceptive use level when other factors were controlled for.

The findings from this study indicate that among the factors associated with contraceptive use, age, marital status, number of children, address and psychoeducation received from health professionals showed significant association with contraceptive use both in univariate and multivariable analyses.

Table 3: determinant factors of Teratogenic risk awareness of the respondents, 2021

characteristics	Awareness of the teratogenic risk		COR(95%CI)	AOR(95%CI)	p-value
	Yes	No			
Age in years					
<30	40(10.4)	107(27.9)	1	1	
30- 39	91(23.7)	94(24.5)	2.70(1.71,4.26)	1.36(0.74,2.46)	
40- 49	22(5.7)	30(7.8)	1.74(0.91,3.34)	0.79(0.34-1.87)	0.252
Marital status					
Married	51(13.3)	48(12.5)	1	1	
Single	49(12.8)	131(34.1)	0.33(0.20,0.56)	0.60(0.28,1.29)	0.264
Divorced or widowed	56(14.6)	49(12.8)	1.07(0.62,1.86)	0.66(0.35,1.23)	
Number of children					
No child	49(12.8)	141(36.7)	1	1	
1 child to 2 children	93(24.5)	78(20.3)	3.41(2.19,5.29)	1.90(0.89,4.02)	0.245
More than 2 children	14(3.6)	9(2.3)	5.11(2.05,12.77)	1.84(0.55,6.13)	
Mood stabilizer treatment					
Sodium valpr.	118(30.7)	153(39.8)	1	1	
Carbamazepine or lithium	32(8.3)	65(16.9)	0.64(0.39,1.04)	0.65(0.38,1.12)	0.042
Not on mood stab	2(0.5)	14(3.6)	0.19(0.04,0.83)	0.18(0035,0.88)	

N.B: - These variables in the table are those found to be significantly associated in univariable analysis which were picked for multiple logistic regression.

Table 4: factors associated with contraceptive use of the respondents, 2021

characteristics	Contraceptive use		COR	AOR	P value
	Yes	no			
Age in years					
<30	32(8.33)	136(35.42)	1	1	0.005
30- 39	93(24.23)	71(18.5)	5.57(3.39,9.12)	1.91(0.98,3.70)	
40- 49	22(5.7)	30(7.8)	3.12(1.59,6.10)	0.59(0.23,1.53)	
Marital status					
Married	59(15.4)	40(10.4)	1	1	0.020
Single	29(7.6)	151(39.3)	0.13(0.74,0.23)	0.32(0.14,0.72)	
Divorced or Widowed	59(15.36)	46(11.98)	0.87(0.49,1.51)	0.61(0.31,1.21)	
Educational level					
Not educated	22(5.7)	14(3,6)	1	1	0.424
Primary education	37(9.6)	55(14.3)	0.43(0.19,0.94)	0.58(0.20,1.67)	
Secondary education	40(10)	90(23.4)	0.28(0.13,0.61)	0.60(0.20,1.80)	
Post secondary education	48(32.7)	78(32.9)	0.39(0.18,0.84)	0.92(0.30,2.82)	
Number of children					

No child	29(7.6)	161(41.9)	1	1	0.013
1 child to 2 children	103(26.8)	68(17.7)	8.41(5.10,13.87)	3.361.49,7.52)	
More than 2 children	15(3.9)	8(2.1)	10.41(4.05,26.78)	2.80(0.71,11.07))	
Address					
urban	100(26.0)	201(52.3)	1	1	0.004
rural	47(12.2)	36(9.4)	2.62(1.59,4.31)	2.97(1.42,6.19)	
Mood stab. Rx					
Sodium valproate	114(29.7)	157(40.9)	1	1	0.099
Carbamazepine or lithium	31(8.1)	66(17.2)	0.65(0.39,1.06)	0.62(0.33,1.17)	
Not on mood stab.	2(0.5)	14(3.6)	0.19(0.04,0.88)	0.22(0.04,1.24)	
Psycho education received from health professional					
no	54(14.1)	182(47.2)	1	1	0.000
yes	93(24.2)	55(14.3)	5.69(3.63,8.95)	3.80(2.23,6.48)	

N.B:

- These variables in the table are those found to be significantly associated in univariable analysis which were picked for multiple logistic regression

12 Discussion

In this study, a total of 384 adult out-patient reproductive age women with bipolar disorder diagnosis, who had follow up at Amanuel specialized mental hospital participated. The objective

of the study was to evaluate the participants' awareness about teratogenic risk of mood stabilizer treatment, their contraceptive use practice and identify the socio-demographic and clinical factors affecting their teratogenic risk awareness and contraceptive use.

In the current study it was found that, women with bipolar disorder were less likely to have awareness about teratogenic risks and have low contraceptive use practice. Only 39.6 % of 384 participants reported that they are aware that their medication could harm their child's health or growth if they take their medication while being pregnant.38.5% of participants reported that they received psychoeducation about risk of teratogenicity with their medication and about importance of contraceptive use.

It is difficult to compare the results of the current study findings with the results of studies done in other countries mainly because the study participants who were included in published literatures were nonpsychiatric patients who are different from our study population.

However, the finding from this study was comparable to the low level of awareness (33.3%) which was reported in study done in Ireland among women with mental illness who were taking Sodium valproate (21). In our study 38.5% of the participants reported that they have received psychoeducation during their treatment period which is comparable to the result reported in the study that was done in Ireland which was 41.9%.

In a study done in USA, 45% of 154 patients taking category C antiepileptic and 40 % of 50 patients taking category D medications reported that they are unaware that their medication could harm their baby (18).

In another study done in UK in 2016, out of 2788 female participants with epilepsy 20% reported that they don't have awareness that their medication could harm their baby if they take the medication while pregnant(19), in similar study 27% of the participants reported that they never received psychoeducation about teratogenic risk related to their medications.

In another study conducted in German speaking countries it was reported that 41% of the participants taking Sodium valproate reported being unaware of its teratogenicity. (20)

Comparing the results of our study with the above mentioned studies, there is relatively higher level of reported awareness among patients with epilepsy in developed countries. This difference might be due to the setting where the studies were done where there is good

quality of health care, strong psychoeducation service given, availability of different information sources, better educational and economic levels.

In this study low number (38.5%) of the 384 participants reported that they received psychoeducation about teratogenic risk of mood stabilizer treatment, the need contraceptive use and this might be due to factors such as difficulty to give adequate psycho education consistently to the high number of patients attending AMSH, liability to recall bias and because there is poor communication between patients medical professionals patients might also do not know what investigations were done before treatment initiation.

Unlike previous study done in Ireland, age is not associated with teratogenic risk awareness (21)

In this study 38.28% of the participants reported that they use contraceptive which is lower than the reports from studies done in Turkey and Brazil (96.6%, 58.8% respectively (22,23).But the results are similar to the report from a study conducted on women with severe mental illness in Addis Ababa (24). The reasons for this comparable figure might be the similarity of the settings where patients are living and being treated.

A study from Nigeria reported lower level of family planning use (27%) when compared to this study.

According to a study conducted at the University of Colorado Hospital in the United States,30/115(26%) of women had a recorded contraceptive use which is slightly lower than the figure in our study and differences in the sociodemographic, sample size, and study design might have contributed to these differences and also there might be difference in the practice of professionals working in the field of Psychiatry and Neurology so conducting comparative study might give an answer. 15(50%) of the 30 patients were using an oral combined hormonal contraceptive, 3(10%) were using a progestin-only pill or implant which was put as a risk factor for contraceptive failure leading to unplanned pregnancy and exposure of the fetus to teratogenic drugs(17). Where as in our study the most frequently used method of contraception were implants (48.9%; n = 72), injectables (42.17%; n = 62) and oral contraceptive pills (4%; n = 6) the result from our study is also different from study done in Addis Ababa on women with severe mental illnesses which reported hormonal contraceptive injectable and pills as the most frequently used contraceptive methods (24).

In the study, majority of the women on mood stabilizers were reported to be taking sodium valproate which is known as one of the AED that does not induce enzymes and interact with the hormonal contraceptives resulting in contraceptive failure but in the study it was not assessed whether the patients on hormonal contraceptive were taking an AED that has an interaction with their medication.

The reasons for the lower levels of contraceptive use practice in women with bipolar disorder were not explored in the study, but may be explained by poorer access to sexual and reproductive health service and lower educational level of majority of the participants. Age, education, marital status and occupation of women were not associated with family planning use in a study done in Addis Ababa (24) where as in this study marital status and address were associated with contraceptive use. In the study done in brazil educational level, income and use of mood stabilizer were not associated with contraceptive use (23) which is similar to our study.

95.83% of the participants were taking one or more mood stabilizers and 81.8 % of them reported that they took their medication for long period(more than six months), considering the low prevalence of contraceptive use among the participants there is a risk for unintended pregnancy and exposure of the fetus to teratogenic medications.

Limitations

Convenience sampling of patients who are actively coming for follow up visits might have resulted in selection bias and could have excluded those who might have defaulted their treatment and follow up as a whole. Recall bias should also be considered in this study as some of the variables may have been affected by participants' cognitive states.

This hospital-based cross-sectional study design might not establish cause and effect relationship in showing a temporal effect on teratogenic risk awareness and contraceptive use level; thus, the findings from this study need to be rechecked in a prospective study.

In addition, we also acknowledge the presence of several other factors that were not taken as variables in this study, which could be important predictors of risk awareness and contraceptive use level among reproductive age women with bipolar disorders; taking other variables into the predictive model is worth exploring in future studies.

13 Conclusions

In general, despite its limitations, this study showed that there is low level of awareness about teratogenic risk of mood stabilizer treatment and low level of contraceptive use practice among women with bipolar illness attending outpatient clinics at Amanuel specialized mental hospital.

Psychoeducation practice about teratogenic risk of mood stabilizer treatment, importance of contraceptive use and pregnancy planning for women who are being treated for bipolar disorders should be strengthened.

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15 ANNEXES

Information sheet and consent form

Addis Ababa University, college of health sciences, Department of Psychiatry

My name is Dr.Tigist Hailiye. I am a third year psychiatry resident. I am doing my research on the topic "teratogenic risk awareness and practice of contraceptive use of female patients with bipolar disorder diagnosis in Amanuel Specialized Mental Hospital". Your participation is very important for the successful completion of this study.

The information will be collected from the questionnaire that you are going to complete. There won't be any harm of completing the questionnaires as long as the confidentiality is kept. To keep the confidentiality, your name is not going to be registered; the questionnaire will be placed into communal envelope after completion.

Would you agree to participate in this study?

1) I agree. ____ 2) I disagree. _____

Questionnaires

Basic Socio-demographic and job description information

a. Age in years _____

b. Marital status:

1) Married
2) Single
3) Divorced
4) Widowed

C. Number of children: _____

d. Educational level

a. Did not attended school
b. elementary school
c. secondary school
d. post-secondary school

e.Occupation _____

f. Address

1) urban 2) rural

g. Religion 1) Christian 2) Muslim 3)other

1. Diagnosis?
2. What is the medication that you are taking currently?
   a. Sodium valproate
   b. Carbamazepine
   c. Lamotrigine
   d. Lithium
   e. Other
3. Duration of treatment with current medication(AED)
   a. <6 months
   b. 6 months and more
4. Is there any additional medication that you are taking?
   a. Yes , list all
   b. No
5. Have you heard of any harm to the fetus due to this antiepileptic drug?
   a. Yes
   b. no
6. If yes, please list the harms that you know
7. From where did you get the information?
   a. From friends
   b. From health care provider
   c. From internet
   d. From news
8. Do you use any type of contraceptives?
   a. Yes
   b. No

9. What type of contraceptive are you using currently?
    a. OC
    b. Depot injection
    c. Implanon
    d. IUCD
    e. Partner Vasectomy
    f. Tubal ligation
    g. Condom
    h. Other
10. pattern of contraceptive use
    a. Consistently
    b. Inconsistently
11. If answer to question number 7 is no, what are the factors affecting use of contraceptive.
    a. Because of my religion
    b. Because of my attitude
    c. I don't know that I have to use contraception
    d. other ,specify
12. Have you ever received psychoeducation about the importance of taking contraceptives while on treatment?
13. Are you currently pregnant?
14. How many pregnancies did you have so far?
15. How many miscarriages, induced abortions or still births did you have so far?
16. Any psychoeducation received previously about teratogenic effect of current medication

a. None
b. Occasionally
c. Multiple times
d. I do not remember

17. Do you have any information whether pregnancy test was done before initiation of treatment or not?

a. Yes
b. No

18. Any pregnancy while taking mood stabilizer?

a. Yes
b. No

19. Do you take folic acid?
    a. Yes
    b. no
20. Do you have epilepsy?

በአ/አዩንቨርስቲጤናሳይንስኮሌጅየስነአእምሮትምህርትክፍል

የፈቃድ መጠየቂያ ቅፅ እና ጥያቄዎች

ስሜ ዶ/ር ትዕግስት ኃይልዬ ስሆን የስነአእምሮ ህክምና ስፔሻሊስት ራዚደንት ሃኪም ነኝ፡፡ ንቃተህሊናና እርግዝና መከላከያ አጠቃቀም የአእምሮ ህክምና መድሀኒት በሚወስዱ ሴቶች መካከል በሚል ርዕስ ላይ ጥናት እያካሄድኩ እገኛለሁ፡፡በመሆኑም ለጥናቱ መሳካት የእርስዎ ተሳትፎ አስፈላጊ ነዉ፡፡በቅድሚያየሚሰጡት ምላሽ ሚስጥራዊነቱ የተጠበቀ መሆኑን ላረጋግጥሎት እወዳለሁ፡፡

በዚህጥናትለመሳተፍፈቃደኛነዎት;

ዐዎ ☐

እምቢ ☐

1. **መሰረታዊ**

ሀ. እድሜ 18 - 28 ☐ 29- 38 ☐ 39-49 ☐

ለ. የጋብቻሁኔታ

ያገባች☐ **ያላገባች**☐ **የፈታች**☐ **ባሏየ**☐

ሐ. የልጆችብዛት ☐

መ. የትምህርትደረጃ

መጀመሪያደረ☐ **ሁለ**☐**ኛ** ☐ **ከሁለተኛደረጃበላይ**☐

ያልተማረ

ሠ. ስራ፡ ☐

ረ. አድራሻ፡ከተማ ☐ **ገጠር**☐

ሰ. ሀይማኖት፡ክርስቲያን ☐ ☐ **ሙስሊም**☐

ሌላ

2. **ህመሙንተ**(diagnosis) ☐

3. **አሁንምንዓይነትመድሀኒትነውየሚወስዱት?**

ሰዲየምሽልፓሬትካርቦ ርንላሞትሪጂንሌላ

4. ለምንያህልጊዜይህንንመድሀኒትወሰዱ?

ከ3 ወርበታች ለ3-6 ወ ለ6 ወር- 1ዓ ከ1ዓመትበላ

5. ሌላ ሚወስዱትመድሀኒትካለ?

አዎ፣ይጥቀሱ የለም

6. የሚወስዱትመድሀኒትዕንስላይምንሊያመጣእንደሚችልሚዉቁትነገርአለ?

አዎ የለም

7. መረጃውንከየትአገኙት?

ከጓደኞቼ ከህክምናባለሙያ ከኢንተርኔ ከዜናሰማ

8. የወሊድመከላከያይጠቀማሉ?

አዎ አልጠቀምም

9. ለተ.ቁ. 10. መልስዎአዎከሆነምንአይነትየወሊድመከላከያይጠቀማሉ?

ኪኒን በመርፌ ክንድውስጥየሚቀበር

በማህጸንውስጥየሚቀመጥ የባለቤቴንየዘርቱቦበማዘጋት

ኮንዶም ሌላ

10. ወሊድመከላከያንእንዴትይጠቀማሉ?

ሁልጊዜ አልፎአልፎ

11. ለምንየወሊድመከላከያአይጠቀሙም (የማይጠቀሙከሆነብቻ)

ሀይማኖቴስለማይፈቅድ ስለማላምንበ

መጠቀምእንዳለብኝአላውቅም ሌላምክንያትይጥቀሱ

12. አሁን የሚወስዱትን መድሃኒት እየወሰዱ የወሊድ መከላከያ መዉሰድ እንዳለብዎ ትምህርት ተሰጥትዎት ያዉቃል?

13. በአሁኑ ሰአት ነፍሰጡርነዎት?

14. እስካሁን ስንት ጊዚ አርግዘዉ ያዉቃሉ?

15. ስንት ጊዚ ዉረጃ ተከስቶቦት ወይም ህይዎት የለለዉ ልጅ ወልደዉ ያዉቃሉ?

16. የስነአእምሮ መድሀኒቶች ዕንስ ላይ ጉዳት እንደሚ ያመጡ ትምህርት ተሰጥቶት ያውቃል?

አያውቅም አልፎአልፎ

ብዙጊዜ ☐ አላስታውስም ☐

17. መድሀኒት ከመጀመርዎበፊትየእርግዝና ምርመራ ተደርጎሎት ነበር?

አዎ☐ አልተደረገም ☐ አላስታውስም ☐

18. አሁን የሚወስዱትን መድሀኒት እየወሰዱ እርግዝና ተከስቶ ያውቃል?

አዎ ☐ አያውቅም ☐

19. ፎሊክ አሲድ ይወስደሉ?

አዎ ☐ አልወስድም ☐

20. የሚጥል ህመም አለብዎ?

ለአእምሮ ህመም ህክምና የሚሰጡ መድሃኒቶች በፅንስ እንዲሁም በልጆች እድገት ላይ ሊያደርሱት ስለሚችሉት ጉዳት የቀረበ አጭር መረጃ

የአእምሮ ህመሞችን ለማከም የሚሰጡ የተለያዩ መድሃኒቶች ሲኖሩ ከነዚህ መካከል የስሜት መዋዠቅን ለማከም የሚረዱ መድሃኒቶች በእንግሊዝኛ ሙድ ስታብላይዘርስ ()፣ አንቲሳይኮቲክስ፣ ድባቴን ለማከም የሚረዱ መድሃኒቶች() የሚጠቀሱ ናቸዉ።

እነዚህ መድሃኒቶች በእርግዝና ወቅት ሲወሰዱ በጥንሱ ላይ ጉዳት ሊያስከትሉ፣ ጉዳት ላያስከትሉ ወይም ያልታወቀ ዉጥት ሊኖራቸዉ ይችላል።

ከላይ ከተጠቀሱት የመድሃኒት አይነቶች መካከል የስሜት መዋዠቅን ለማከም የሚረዱት መድሃኒቶች() በጥንስ ላይ ጉዳት ወይም ልጆች ከተወለዱ በሁዋላ የተለያዩ ችግሮችን ሊያስከትሉ እንደሚችሉ በብዙ ጥናቶች ተረጋግጥዋል።

ሊያስከትሉ ከሚችሉዋቸዉ ችግሮች መካከል የሚከተሉት ይገኙበታል

- በልብ ላይ ችግር መኖር

- የጀርባ አጥንት ክፍት ሆኖ መወለድ እና ከዚህ ጋር ተያይዘዉ የሚመጡ ችግሮች
- የላንቃ እና ከንፈር ክፍት ሆኖ መወለድ
- የወንድ ህፃን ውጫዊ ብልት ላይ ችግር መኖር
- የህፃናት የጭንቅላት ክፍተቶች በቶሎ (ያለጊዚያቸዉ) እንዲዘጉ በማድረግ የአእምሮ እድገትን መወሰን
- ከተወለዱ በሁዋላ ለተለያዩ የእድገት እና የባህሪ ችግሮች መጋለጥ እና ሊሎች ያልተጠቀሱ ችግሮች

በመሆኑም በመራቢያ የእድሚ ክልል ላይ ያሉ እና እነዚህን መድሃኒቶች መዉሰድ ያለባቸው ሲቶች ከላይ የተጠቀሰዉ መረጃ በበቂ ሁኒታ ሊኖራቸው ይገባል እንዲሁም የበተሰብ እቅድ መመራት፣ አስተማማኝ እና ዘላቂ የወሊድ መከላከያ መጠቀም፣ ፎሊክ አሲድ የተባለ ቫይታሚን መዉሰድ ይኖርባቸዋል።

ከላይ ስለተጠቀሱት መረጃዎች እንዲሁም እርስዎ ማድረግ ስለሚገባዎ ጥንቃቄዎች ለማወቅ ከሃኪምዎ ጋር ተጨማሪ ዉይይት እንዲያደርጉ እንመክራለን።