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EFFECTIVENESS ANALYSIS OF ANTIDEPRESSANTS IN THE MAJOR DEPRESSIVE DISORDER: A PROSPECTIVE OBSERVATIONAL STUDY

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ABSTRACT: Background: Major Depressive Disorder (MDD) is a severe psychiatric illness characterized by persistent sadness, loss of interest, lack of energy, disturbed sleep and suicidality with lifetime prevalence rate for MDD is 16.2%. Treatment options for depression include medication, primarily antidepressants, and psychotherapy. **Method:** A prospective observational questionaire based study was conducted in psychiatric department of VIMSAR, Burla taking 50 patients diagnosed with MDD for a period of 24months. Effect on QOL was evaluated using WHOQOL (BREF) Questionairre, CGI-S, CGI-I and MADRAS scores. **Results:** Dosulepin/Dothiepin (TCA) was most frequently prescribed antidepressant followed by escitalopram (SSRI). The efficacy of SSRIs is equivalent to that of TCAs. There was no significant difference among the four antidepressants with regard to reductions in the total scores on CGI-S, CGI-I and MADRS scales. **Conclusion:** Antidepressants used for therapy of MDD in our study were effective in QOL improvement, better compliance on long term basis except for side effect profile.

INTRODUCTION: Depression is a major public health problem in India, contributing to significant morbidity, disability as well as mortality, along with significant socioeconomic losses. Globally, an estimated 322 million were affected by depression in 2015. Depression is ranked as the single largest contributor to non-fatal health loss, accounting for 7.5% of global years lived with disability (YLDs) and 2.0% of global disability adjusted life years (DALYs) in 2015.

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The burden of depression (DALYs) increased by 67% between 1990 and 2013; and by 2025, DALYs attributable to depression are projected to rise by roughly 2.6 million 11 (22.5%) due to population growth and ageing. Globally, the proportion of the population with depression is estimated to be 4.4%; common among females 5.1% vs 3.6% with a peak in the 55–74-year age group in both sexes. Depression at its worst can lead to suicide.

The association of depression and suicides are well established and studies have shown the probability of deaths from suicide among depressed hospitalized patients to be 15% [1]. Major Depressive Disorder (MDD) is a severe psychiatric illness characterized by persistent sadness, loss of interest, lack of energy, disturbed sleep and suicidality. The lifetime prevalence rate for MDD is 16.2% in most

developed countries. Approximately 15%-45% of MDD patients suffer from a chronic, unremitting course of depression despite receiving multiple antidepressant medications.

The outcome of depression can be significantly improved by early detection. Treatment options for depression include medication, primarily antidepressants, psychotherapy which includes cognitive-behavioral therapy (CBT), interpersonal therapy (IPT) and electroconvulsive therapy. Most common treatments are medications and psychotherapy [2]. Antidepressants are a class of drugs used primarily in the management of depressive disorders and anxiety disorders. However, this class of drugs is also used for the management of sexual dysfunction, eating disorders, impulse control disorders, enuresis, aggression and some personality disorders [3]. Several different classes of antidepressants are available for treating depression. These include selective serotonin reuptake inhibitors (SSRIs), selective norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs) and monoamine oxidase inhibitors (MAOIs). Selection of appropriate antidepressants will largely based on side effects, safety or tolerability for individual patients [4]. The SSRIs and other newer antidepressants (e.g. nefazodone, venlafaxine *etc*.) have comparable clinical efficacy, better tolerability, favorable safety and earlier onset of action [5].

While there is enough data available on the clinical efficacy of antidepressants used for the treatment of depression, both as monotherapy or in form of combination therapy, there is lack of information regarding the effect of medications used to treat depression on health- related quality of life, patient-reported mental health status and psychological distress. Health-related quality of life (HRQOL) is a multi-dimensional concept that includes domains related to physical, mental, emotional and social functioning of an individual [6]. The current study will not only assess the effectiveness of antidepressants on HRQOL but will also enumerate the adverse effects of various classes of antidepressants in the treatment of MDD.

Objectives of the Study: The present study was undertaken in VIMSAR, Burla, a tertiary care hospital, in patients with diagnosis of major depression, according to ICD- 10 criteria with the following objectives:

1. To assess the effects of antidepressants on QOL of patients in MDD.
2. To study the drug utilization pattern of antidepressants.

MATERIAL & METHODS:

Place of Study: VIMSAR, Burla, Sambalpur, Odisha.

Setting of Study: Department of Psychiatry (OPD/IPD).

Period of Study: 24 months (October 2019 - September 2021) The last date for recruitment of patients shall be on 31st July 2020.

Study Design: Prospective, Observational, and Questionnaire based study:

- Effect on QOL to be evaluated using WHOQOL (BREF) Questionaire, CGI-S, CGI-I and MADRAS scores

Study Population: Patients on antidepressants for MDD

Sample Size: 50 patients suffering from MDD

Sampling Technique: Convinience sampling

Selection Criteria:

Selection Criteria:	
Inclusion criteria	**Exclusion criteria**
Patients with MDD aged 18-65years Substance Abuse	Patients with Significant Disability Medical co-morbidity Dependance disorder Eating disorder Personality disorder

Study Tools and Techniques:

1. WHOQOL (BREF) Questionnaire
2. MADRS, CGI-I and CGI-S scales

Intervention: Nil

Study Varibles:

Demographic variables:

- Age
- Gender
- Religion
- Ethnicity
- Education
- Employment status
- Marital status

Patient responses to questions of WHOQOL (BREF) Questionaire, CGI-S, CGI-I scales and MADRS scale analysis

Data collection Methods: A detailed history of all registered patients was recorded. A thorough clinical examination was conducted for all patients by a psychiatrist. The patients were given treatment for a period of 4 weeks and were followed up.

Clinical assessment for efficacy, response rates and safety parameters of antidepressants were done at the beginning of the study (Baseline) and after 1 month and 6 months respectively.

Effectiveness Assessment of Antidepressants: Clinical Global Impression – Severity scale (CGI-S).

Rated on the following 7 point scale:

1. Normal, not at all ill

2. Borderline mentally ill

3. Mildly ill

4. Moderately ill

5. Markedly ill

6. Severely ill

7. Among the most extremely ill patients

This rating is based upon observed and reported symptoms, behavior and function in the past seven days. Clinical Global Impression- Improvement scale (CGI-I).

The CGI-I is similarly simple in its format. Each time the patient is seen after medication has been initiated, the clinician compares the patients overall clinical condition to the one week period just prior to initiation of medication use.

1. Very much improved since initiation of treatment

2. Much improved

3. Minimally improved

4. No change from baseline

5. Minimally worse

6. Much worse

7. Very much worse since the initiation of treatment

MADRS (Montgomery Åsberg Depression Rating Scale): The main purpose of this scale is to assess depressive symptom logy, particularly change in patients treated with antidepressants. MADRS focuses on the psychological symptoms of depression (e.g., sadness, tension, and pessimistic thoughts).

This scale is clinician-rated and consists of 10 items; each item is rated on a 0-6 scale, resulting in a maximum total score of 60 points, with higher scores indicative of greater depressive symptomology. The MADRS scoring instructions indicate that a total score ranging from 0 to 6 indicates that the patient is in the normal range (no depression), a score ranging from 7 to 19 indicates “mild depression,” 20 to 34 indicates “moderate depression,” a score of 35 and greater indicates “severe depression,” and a total score of 60 or greater indicates “very severe depression.”

Efficacy was assessed by measuring the reductions in the WHO-BREF scores at the end of the study (6months) from baseline scores. Early response rate was assessed by measuring the reductions of total WHO-BREF scores at month of the study from baseline scores. The safety profile was assessed by studying the adverse effects in the patients of both a standard adverse effect checklist prepared, based on previous literature, for the study.

Whoqol-Bref Scale: WHOQOL-100 allows a detailed assessment of individual facets relating to quality of life, it may be too lengthy for practical uses. In these instances, assessments will be more willingly incorporated into studies if they are brief, convenient and accurate. The WHOQOL-BREF provides a short form QOL assessment that looks at Domain level profiles, using data from the pilot

WHOQOL assessment and all the available data from the Field Trial Version of the WHOQOL-100.

Scoring of Whoqol Bref: The WHOQOL-BREF produces four domain scores. There are also two items that are examined separately: question 1 asks about an individual's overall perception of quality of life and question 2 asks about an individual's overall perception of his or her health.

Domain scores are scaled in a positive direction (*i.e.* higher scores denote higher quality of life). The mean score of items within each domain is used to calculate the domain score. Mean scores are then multiplied by 4 in order to make domain scores comparable with the scores used in the WHOQOL-100, and subsequently transformed to a 0-100 scale, using the formula above. A method for the manual calculation of individual scores is below:

Physical domain = (6-Q3) + (6-Q4) + Q10 + Q15 + Q16 + Q17 + Q18) x4

Psychological domain = (Q5 + Q6 + Q7 + Q11 + Q19 + (6-Q26) x4

Social Relationships domain = (Q20 + Q21 + Q22) x4

Environment domain = (Q8 + Q9 + Q12 + Q13 + Q14 + Q23 + Q24 + Q25) x4

Transformation of Scores to A0 - 100 Scale: Domain scores can be transformed to a 0-100 scale using the following formula:

Transformed Score = (SCORE-4) x (100/16)

Data Analysis: The data collected was entered into MS Excel. The stastical analysis was done using SPSS Software version 21.0. Results were expressed as mean ±SEM. The quality-of-life scores on WHOQOL-BREF scale and assessment of severity and subsequent improvement with various antidepressants on CGI-S, CGI-I and MADRS were examined and differences between medians were assessed by using non parametric test (Friedmann, s test, Wilcoxan signed rank test) using the SPSS Software vesion 21.0. A p value <0.05 was considered as stastically significant.

OBSERVATION AND RESULTS: This prospective observational study was conducted over a period of 24 months (October 2019-September 2021) in the Department of Psychiatry and Department of Pharmacology of V.S.S .Institute of Medical Sciences and Research, Burla, Odisha. The following observations were made as regards the effects of various antidepressants on the improvement in quality of life of patients suffering from MDD.

During the study period, 50 cases of MDD were enrolled into the study and were followed up for a period of 6months while on treatment with conventional antidepressants.

Demographic Profile of Patients: Out of the 50 cases, majority of patients belonged to the middle age group (41-50yeas) [16, (32%)]; (51-60years) [16, (32%)] followed by 31-40 years age group [12, (24%)] and 21-30 years age group [5, (10%)] and only one elderly case (2%) as shown in **Table 1.** Out of 50 cases, 35 (70%) were females and 15 (30%) were males as depicted in **Fig. 1.**

TABLE 1: AGE DISTRIBUTION OF MDD PATIENTS

Age (years)	No./Percentage of cases
20-30	5(10%)
31-40	12 (24%)
41-50	16(32%)
51-60	16(32%)
61-70	1(2%)

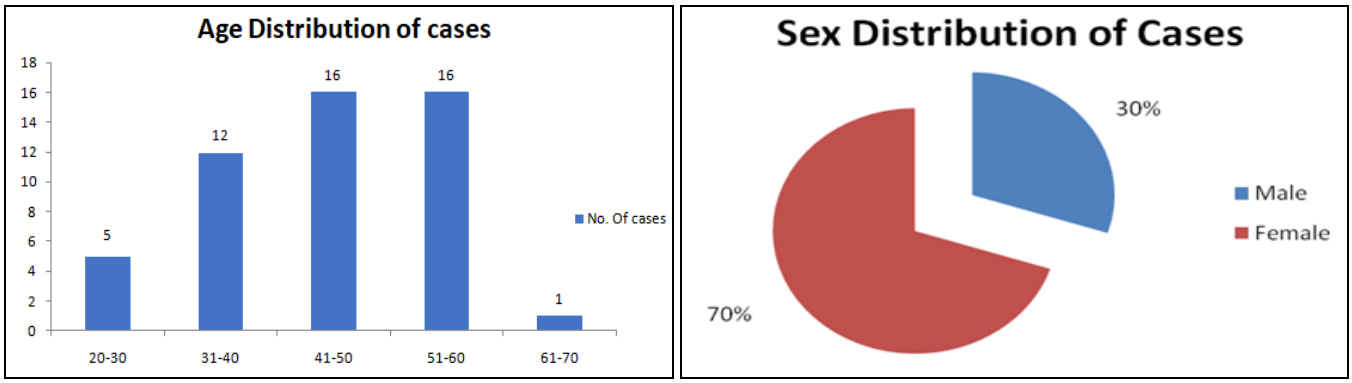

FIG. 1: SEX DISTRIBUTION OF CASES

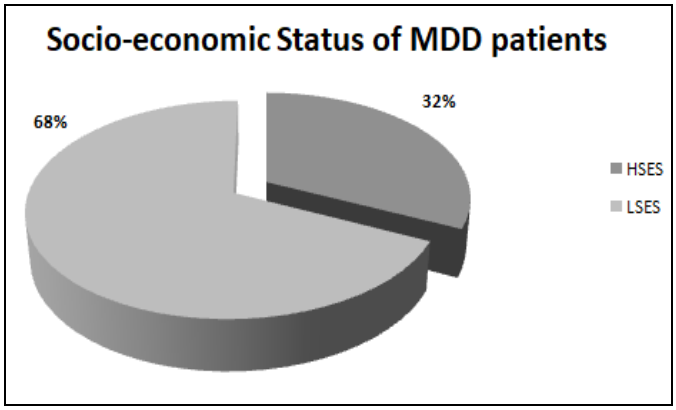

FIG. 2: SOCIO-ECONOMIC STATUS OF MDD PATIENTS

Majority of patients belonged to low socio-economic status (64%) as shown in **Fig. 3.** Out of the 50 cases, 35 (70%) were unemployed (housewives), 7 (14%) were servicemen, 6 (12%) people were farmers and remaining 2 (4%) were self employed as depicted in **Fig. 4.**

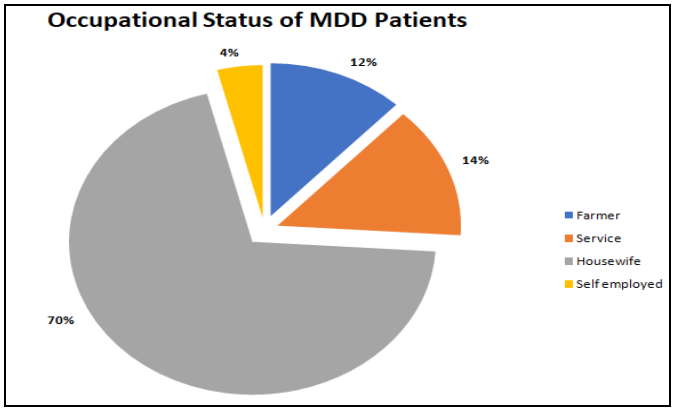

FIG. 3: OCCUPATIONAL STATUS OF MDD PATIENTS

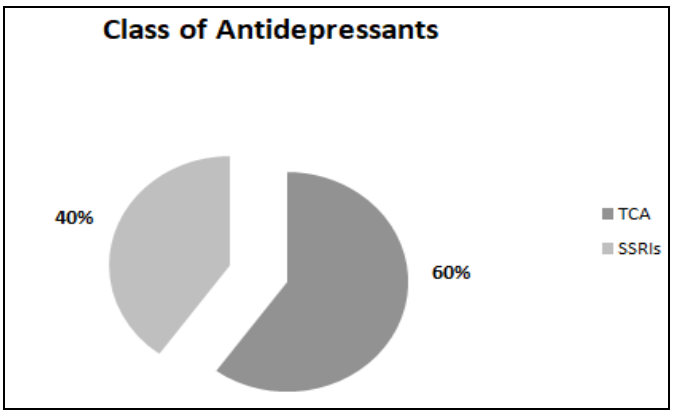

FIG. 4: CLASS OF ANTIDEPRESSANTS USED IN MDD

The antidepressants prescribed during the course of treatment were dothiepin [24 patients (48%)], escitalopram [16 patients (32%), amitryptilline [6 patients (12%)] and sertraline [4patients (8%)] as depicted in table 3.'Thus, 60 % patients received TCA and 40% received SSRIs as shown below in **Fig. 5.**

TABLE 2: ANTIDEPRESSANTS USED IN MDD PATIENTS

Antidepressant	No./Percentage of Patients
Dothiepin	24 (48%)
Escitalopram	16 (32%)
Amitriptiline	6 (12%)
Sertraline	4 (8%)

Result of Assessment of Effectiveness of Antidepressants on QOL of Patients Using the WHOQOL BREF Scale: The comparison of effectiveness of antidepressants was made by using the CGI-S scale which measures the severity of disease, CGI-I scale which measures improvement in disease condition, MADRS scale which measures effectiveness of antidepressant therapy and WHOQOL-BREF scale which measures quality of life of patients under four domains *i.e*, physical health, psychological, social relationship and environment at baseline, 1month and 6 months by using non parametric, paired t-test (Wilcoxon signed rank test) followed by intergroup comparison using Friedman test. All the four scaled showed significant improvement with antidepressants as shown in tables below.

TABLE 3: WHOQOL-BREF SCALE SCORES AT BASELINE, 1 MONTH AND 6 MONTHS OF ANTIDEPRESSANT THERAPY

Whoqol-Bref Domains	Baseline (Mean±SEM)	1 month (Mean±SEM)	6 month (Mean±SEM)	p value	
				0-1month	0-6month
Physical	416±7.97	484.50±7.35	496.00±7.01	0.002**	0.000***
Psychological	413±7.29	441.50±5.51	448±5.09	0.002**	0.001**
Social	196±4.96	214.50±4.10	216±4.025	0.001**	0.001**

Environmental	535±11.49	593±8.80	606.50±8.23	0.002***	0.001**

(If higher the score, the effectiveness is better with WHOQOL-BREF scale and worse with CGI-S, CGI-I and MADRS scale). *p < 0.05 = stasticallysignificant; **p < 0.01 = highly significant;*** p < 0.001 = very highly significant.

TABLE 4: CGI-S, CGI-I AND MADRS SCALE SCORES AT BASELINE, 1 MONTH AND 6 MONTHS OF ANTIDEPRESSANT THERAPY

Sl. no.	Scales	Mean score at baseline (Mean± SEM)	Mean score at 1month of antidepressant therapy (Mean± SEM)	Mean score at 6months of antidepressant therapy (Mean ± SEM)	Level of Significance
1	CGI-S	3.92±0.10	3.42±0.86	2.52±0.91	.000***
2	CGI-I	2.70±0.06	2.20±0.06	1.60±0.80	.001***
3	MADRS	35.76±1.09	26.40±0.91	17.38±0.48	0.001***

*p < 0.05 = stasticallysignificant; **p < 0.01 = highly significant;*** p < 0.001 = very highly significant

TABLE 5: CGI-S, CGI-I AND MADRS SCALE SCORES AT BASELINE, 1 MONTH AND 6 MONTHS OF ANTIDEPRESSANT THERAPY

Sl. no.	Scales	Mean score at baseline (Mean± SEM)	Mean score at 1month of antidepressant therapy (Mean± SEM)	Mean score at 6months of antidepressant therapy (Mean ± SEM)	Level of Significance
1	CGI-S	3.92±0.10	3.42±0.86	2.52±0.91	.000***
2	CGI-I	2.70±0.06	2.20±0.06	1.60±0.80	.001***
3	MADRS	35.76±1.09	26.40±0.91	17.38±0.48	0.001***

*p < 0.05 = stasticallysignificant; **p < 0.01 = highly significant;*** p < 0.001 = very highly significant.

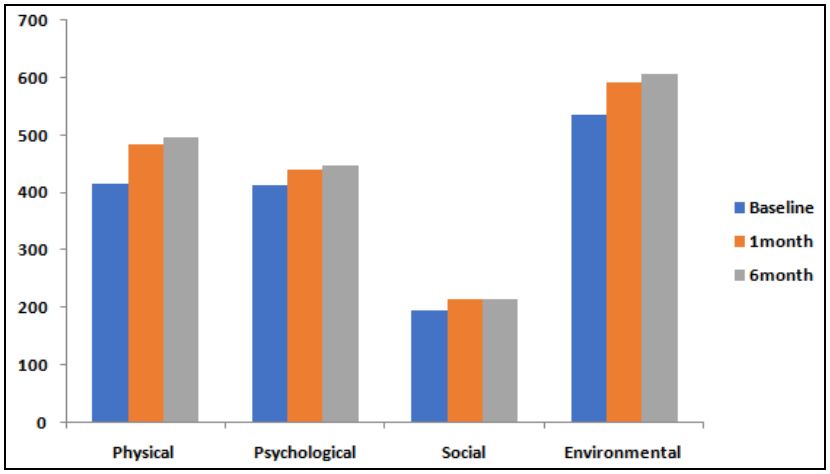

FIG. 5: COMPARISON OF VARIOUS DOMAINSCORES AT BASELINE, 1MONTH AND 6MONTHS USING WHOQOL-BREF SCALE

DISCUSSION: This prospective observational study intended to compare the effectiveness of antidepressants in our Tertiary Care Hospital by following up patients under treatment for MDD, and observed the course of severity of disease, improvement of disease and change in quality of life after a period of 1month and 6months respectively. In this study population, age distribution revealed most of the patients were from (41-50yeas) age group (32%); (51-60years) age group (32%) followed by 31-40 years age group (24%) and 21-30 years age group (10%) and only one elderly case (2%). Epidemiological studies have shown a higher prevalence of all mood disorders among persons under the age of 45 years [7]. The average age of the onset of major depression is between 20 and 40 years [8]. Gender distribution revealed female predomination in our study. This corroborates with the study conducted by Yu-Chen Chang *et al.* [9] Clinical and epidemiological studies concur in suggesting that women are at higher risk for mood disorders, with the highest risk for depression. Though the specific reasons for this are unknown, certain studies suggest that women have a temperamental inclination to depressive cognitions, might more adversely respond to childhood adversities and are more specifically vulnerable to adult stressors related to bonding with men and child rearing [10]. Also, women over respond to sad circumstances over a lifetime,

thereby permanently altering anterior limbic and prefrontal brain function in a depressive direction. [11]. In the current study, the occupational status of patients is also unsatisfactory and poor occupational status is directly related to low socio-economic status, poor treatment adherence and poor patient care, so poor diagnosis and quality of life. Out of the total cases (70%) were unemployed (housewives), (14%) were servicemen, (12%) people were farmers and remaining (4%) were self employed.

The different antidepressants prescribed to the MDD patients were dosulepine, escitalopram, sertraline and amitryptiline. Other studies in contrast to this study studied the newer antidepressants like vilazodone, vortioxetine, venlafaxine, milnacipran, bupropionetc by Hengartner MP *et al.* [12] But as our study is a government hospital based study, prescription of free drugs is mandatory for the clinicians and also, the other reason for non-prescription of newer antidepressants was their high cost and patients in our study belonged to low socio-economic status.

Dosulepin/Dothiepin (TCA) was most frequently prescribed antidepressant followed by escitalopram (SSRI). The findings corroborate with the studies conducted by Chakrabarti *et al* [13-14] where imipramine was rampantly prescribed followed by fluoxetine. However the result is in contrast to the study done by Tripathi *et al* [15] that showed SSRIs were the most commonly prescribed medications with escitalopram being the first choice.

Clonazepam was the preferred benzodiazepine with antidepressants as evidence from studies has suggested that it has the potential to increase the effects of SSRI and can partially suppress the adverse effects of SSRI [16, 17]. Other sedative and hypnotic used was zolpidem. Patients who reported with poor sleep, appetite disturbances, guilt/self blame and fatigue were more likely to be prescribed with sedatives and hypnotics. The prescription rate of benzodiazepine remains high in our study but may be less in comparison to other Indian studies evaluating prescription patterns in patients with depressive disorders [18, 19]. Comparison of effectiveness of antidepressants was made using CGI-S (Clinical Global Impression – Severity) scale, CGI-I (Clinical Global Impression – Improvement) scale, MADRS (Montgomery-Asberg Depression Rating Scale) and WHOQOL-BREF scale and results showed better improvement in terms of reduction in severity, improvement in disease condition and improvement in quality of life. Result of this study is in corroboration with the study conducted by Selvan *et al* [20] which found that patients with MDD had reduced illness severity as measured by Clinical Global Impression – Severity scale (CGI-S) and improved clinician rated functioning [as measured by Hamilton Depression Rating Scale (HDRS) and Beck Depression Inventory (BDI) scale] after 1 month of treatment. Study conducted by Qin Jiang and Saeeduddin Ahmed also suggested that HAM-D17, MADRS, CGI-S and CGI-I scores presented a consistent picture of response to antidepressant therapy [21].

There was no significant difference among the four antidepressants with regard to reductions in the total scores on CGI-S, CGI-I and MADRS scales. This corroborates with the findings of study done by Janakiramaiah *et al.* [22].

Comparison among all the four domains of WHOQOL-BREF scale showed fastest improvement in physical health domain followed by environment domain and psychological domain and slowest improvement in social relationship domain by the conventional antidepressants. The results of our study in relation to domain improvement is corroborating with the study conducted by Yu-Chen Chang *et al.* [23] This finding indicates the poor performance of older antidepressants so far as improvement in social relationship is concerned. This is obviously an important aspect of drug effect which is deirable. However, it will be interesting to know whether the newer ADDs are effective in this parameter.

This study had some limitations which should be outlined. With its relatively small sample size, select on bias could not be ruled out and bias from unanswered questions might have influenced the outcomes. The effectiveness of newer antidepressants like vilazodone, milnacipran, could not be measured because their higher cost prohibited clinicians to prescribe them. The study was confined to patients attending Department of Psychiatry, VIMSAR, Burla only and may not be generalized to other private clinics / hospitals.

Overall, these results may contribute to clarify the existing controversial data available regarding effectiveness of antidepressants in real world. Based on these findings, it can be said that all the four antidepressants used for therapy of MDD are effective in QOL improvement, better compliance on long term basis except for side effect profile. TCAs (dosulepine and amitryptiline) exhibited adverse reaction more than the SSRIs (escitalopram and sertraline). Because of the availability of many newer antidepressants, and controversial knowledge about their effectiveness, more studies involving other antidepressants, employing other scales and including patients of diverse socio-economic status are needed to get sill deeper insight into the effectiveness of various antidepressants in MDD.

CONCLUSION: The present study was a prospective, observational study conducted in VIMSAR, Burla during the period of October 2019 to September 2021. The ethical permission was obtained from the Institutional Ethics Committee (IEC) of VIMSAR, Burla before the conduct of the study. Fifty patients attending the outpatient Department of Psychiatry with a diagnosis of Major Depressive Disorder, according to ICD – 10 criteria, were screened and enrolled in the study as per inclusion & exclusion criteria. Informed / written consent was taken from all the patients before they were taken up for the study. Efficacy and response rates were assessed by using MDRS, CGI-S and CGI-I Scale and Quality of Life parameters using the WHOQOL-BREF scale. Tolerability and safety profile were evaluated by comparing the adverse effects experienced by the patients with the standard adverse effect check list prepared for the study, based on previous studies and literature. The data was collected in a specially designed proforma which was subjected to statistical analysis.

The results from the study provided the following conclusions:

The incidence of depression was higher among the 41-60 years of age groups. One of the possible triggering factors for depression in these age groups is stress, both domestic and at work. Females were more (70%) in number as compared to males (30%) in both the study groups. This finding reinforces the observations suggesting a female preponderance in mood disorders. A possible role of difference in reacting to sad circumstances coupled with increased domestic pressures in Indian women can be suggested to explain this finding. The efficacy of SSRIs is equivalent to that of TCAs. This finding is in concurrence with studies showing comparable efficacy of SSRIs to the standard, older antidepressants.

Most commonly used antidepressant in our study was dosulepin (TCA) followed by escitalopram (SSRI). Antidepressants were used in conjuction with sedative-hypnotics; mostly clonazepam and zolpidem. Comparison of antidepressants using WHOQOL-BREF scale scores showed no statistically significant difference among them. In the WHOQOL-BREF scale, environmental domain showed maximum improvement followed by physical health domain and least improvement with social domain. Comparing the effectiveness of antidepressants using the CGI-S, CGI-I and MARDS scales at baseline, 1 month and 6months respectively showed minor stastistical differences among the four antidepressants.

Hence, the results of this study revealed that all four antidepressants used for therapy of MDD showed minor statistical differences in effectiveness. However all the antidepressants used were effective in the improvement of QOL in all aspects namely physical health, psychological health, social relationship and environment. But these conclusions should be seen in context of some weakness of this study namely, small sample size, limited duration and lack of variety in the antidepressant drugs prescribed because the setting of this study is a government hospital.

Again because of the availability of many more newer antidepressants and inadequate knowledge about their effectiveness in the real world, much more studies involving these antidepressants , employing other scales, for a longer duration and including patients of diverse socio-economic status are needed to get better insight into the effectiveness of various antidepressants in MDD.

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CONFLICT OF INTEREST: None

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