

Pharmacoepidemiological Profile Of Antidepressant Agents Prescribed For The Treatment Of Newly Diagnosed Cases Of Major Depressive Disorder

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Abstract: Background: Depression is a major public health problem in India, contributing to significant morbidity, disability as well as mortality, along with significant socioeconomic losses. Causes of depression are several, including biological, social, economic and cultural factors, which are triggered by environmental factors. Present study was designed to identify the socioeconomical factors, age and sex distribution and prescribing pattern of antidepressant agents in newly diagnosed cases of Major Depressive Disorder (MDD) in a tertiary care teaching hospital. Method: Prior approval from the Institutional Ethics Committee, permission from Head of Psychiatry department and Medical superintendent of the hospital were taken. Investigator visited OPD and wards of psychiatry department thrice weekly. Patient who met inclusion and exclusion criteria had been enrolled. All the sociodemographic details, clinical presentation as well as prescribed antidepressant agents as well as their dosage regimens were recorded in predesigned and structured case record form. Hamilton depression rating scale (HDRS) and Montgomery and Asberg depression rating scale (MADRS) were recorded in all study participants. Data were analyzed by using appropriate statistical tests. Result: 202 patients were divided into four groups as per the drugs prescribed (Fluoxetine: n=58; Sertraline: n=54; Amitriptyline: n=46 & Desvenlafaxine: n=44). Out of total 202 patients, 109 patients were women and 93 patients were men. Maximum numbers of patients (66.34%) were aged 41 to 60 years. There were 68 illiterate patients. It was observed that the most common presenting complaint was depressed mood (94.1%), followed by loss of interest, anxiety, insomnia, fatigue, lack of concentration, somatic symptoms, guilt and suicide tendency. Conclusion: Higher prevalence of MDD was reported in female, in lower socioeconomic class, in illiterate and elderly. Fluoxetine, Sertraline, Amitriptyline and Desvenlafaxine were the prescribed antidepressant agents. But socioeconomical factors, gender, age were not found to be the determinant factor for the selection of antidepressant agent. [Patel D Natl J Integr Res Med, 2019; 10(6):33-40]

Key Words: Major Depressive Disorder (MDD) Fluoxetine Sertraline Amitriptylin Desvenlafaxine

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Introduction: Depression is a very common mental disease which affects people of all age, sex, religion as well as different socioeconomic class. Globally, an estimated 322 million people were affected by depression in 2015.¹ Around 18% of the global estimate of the depression is in India. Because of urbanization, migration and increased modernization depression is likely to increase in coming years.¹ The burden of depression, in terms of DALYs, increased by 67% between 1990 and 2013. By 2025, DALYs attributable to depression are projected to rise by roughly 2.6 million (22.5%) due to population growth and ageing.²

Depression contributes to significant disease burden at national and global levels. At the individual and family level, depression leads to poor quality of life, causing huge social and economic impact. Globally, depression is the top cause of illness and disability among young and middle-aged populations.³ Depression is associated with poverty in a vicious cycle. It is projected to be the second leading cause of

disease burden globally and third leading cause of disease burden in Low and Medium Income Countries (LMICs) by 2030.⁴

Major depressive disorder (MDD) is characterized by single or recurrent major depressive episode. The essential feature of a major depressive episode is a period of at least 2 weeks of depressed mood with abnormalities of neurovegetative function (appetite, weight loss, sleep disturbances), psychomotor activity (e.g. loss of energy and interests, agitation, or retardation), cognition (feelings of worthlessness, hopelessness, or inappropriate guilt), as well as anxiety and suicidal ideation. Symptoms have to be present most of the day and nearly every day.⁵ An early diagnosis and treatment leads to remission of the disease and prevents relapse. Pharmacological treatment along with supportive psychological intervention is effective in about 80% of patients.⁶ Tricyclic antidepressants, Selective Serotonin Reuptake Inhibitors (SSRIs), Serotonin Nor-epinephrine Reuptake Inhibitors (SNRIs), atypical

antidepressants as well as many newer agents are available in the armamentarium for the pharmacotherapy of depression.^{7,8}

This study was planned to conduct in a psychiatry department of a tertiary care teaching hospital which is having a significant turnover of patients diagnosed as having Major Depressive Disorder (MDD). These patients are prescribed wide range of drugs with different efficacy and safety and considering the fact that very few studies has been done so far in this set up to evaluate the patient's profile and prescribing pattern of antidepressant agents and to find the correlation between them.

Materials And Methods: An observational cross sectional study to analyze the pharmacoepidemiological profile of patients diagnosed as having Major Depressive Disorder (MDD) was conducted in a psychiatry department of a tertiary care teaching hospital over a period of 1 year and 8 months after prior approval of Institutional Ethics Committee and Medical Superintendent of the institute. Voluntary informed consent of all study participants were taken. The investigator visited the OPD and in-patient wards of Psychiatry department thrice a week (Monday, Wednesday, Friday from 9:00 am to 12:00 noon) and enrolled all newly diagnosed patients of major depression based on inclusion and exclusion criteria.

Inclusion Criteria: >20 years in either gender. Patient attending psychiatry OPD / hospitalized patient having major depressive illness. Patient having baseline score of >17 with Hamilton Depression Rating Scale (HDRS) and >34 with Montgomery and Asberg Depression Rating Scale (MADRS). Patient who were willing to participate by giving written informed consent.

Exclusion Criteria: Patients with Axis II personality disorder or mental retardation according to DSM- IV diagnostic criteria. Patients meet DSM-IV criteria for current or past history of Schizophrenia, Paranoid Disorders, or any other Psychotic Disorders. Patients with a first degree relative with bipolar disorder. History of Electroconvulsive therapy (ECT) at any time in the past. Any unstable hepatic, renal, pulmonary, cardiovascular (including uncontrolled hypertension), ophthalmologic, neurological illness. Patient with raised

intraocular pressure or presence of narrow angle glaucoma. Past history of Myocardial infarction.

Demographic details of the patients including age, gender, weight, occupation, and annual income; chief complaints in terms of severity and frequency were recorded in predesigned and validated structured case record form (CRF).

Personal history such as addiction, sleep and appetite disturbance, marital status and the number of children, menstrual history and history of post menopausal syndrome were also recorded in case of female patients. Any concomitant diseases, past history of similar complaints or any other chronic diseases, Family history of psychiatric illness, chronic illness and or any other significant illness were also recorded. Drug treatment – Details of all drugs including their brand name, generic name, dose employed, route, frequency of administration, duration of therapy were recorded in CRF. Data were analyzed in number, percentage and by applying suitable statistical tests.

Results: Out of total 202 patients enrolled during the study period, the patients were divided into 4 groups as per the drug prescribed to them i.e. Fluoxetine (Fluoxetine group), Sertraline (Sertraline group), Amitriptyline (Amitriptyline group), and Desvenlafaxine (Desvenlafaxine group). 58 patients were prescribed Fluoxetine, 54 patients were prescribed Sertraline, 46 patients were prescribed Amitriptyline and 44 patients were prescribed Desvenlafaxine. Male to female ratio is 0.85. Among the four treatment groups, in Fluoxetine group 30 (51.7%) patients were female, in Sertraline group 30 (55.6%) patients female, in Amitriptyline group 25 (54.4%) patients were female and while in Desvenlafaxine group 24 (54.6%) patients were women. When gender distribution was compared between four treatment groups by applying Chi-square test, no significant difference was found

The age of the patients in Fluoxetine group ranges from 28 to 64 years with mean age was 45.4 ± 8.72 years, in Sertraline group age ranges from 26 to 69 years with mean age was 47.4 ± 8.90 years, in Amitriptyline group age ranges from 26 to 62 years with mean age was 44.5 ± 10.25 while in Desvenlafaxine group age ranges from 24 to 65 years with mean age was 45.2 ± 9.18 .

Most common age group was 41 -60 years of age including 134 patients (66.3%) followed by 20-40 years age group including 47 patients (23.3%), >60 years of age including 21 patients (10.4%). When mean age was compared between four treatment groups by applying one way - ANOVA test, no significant difference was found, hence all treatment groups are comparable in terms of age distribution.

There were 68 illiterate patients, of which 20 patients belonged to Fluoxetine group, 18 patients to Sertraline group, 14 patients to Amitriptyline group while 16 patients to Desvenlafaxine group. 36 patients in Fluoxetine had educational qualification of 10th standard and above, Sertraline group had 36, Amitriptyline group had 30 and Desvenlafaxine group had 28 patients with similar qualifications. When educational qualification was compared between four treatment groups by applying Chi-square test, no significant difference was found.

It was observed that majority of the patients in all four treatment groups were housewives (39%), followed by laborers (19%), unemployed (10%), office work (9%), vendors (8%) and rickshaw puller (7%). Occupation of study participants in different treatment group is depicted in table 1.

Table1: Occupation of study participants in different treatment groups (Expressed in numbers)

Occupation	Fluoxetine (n=58)	Sertraline (n=54)	Amitriptyline (n=46)	Desvenlafaxine (n=44)	Total (n=202)
House wife	26	19	18	16	79
Laborers	09	12	10	08	39
Unemployed	06	04	04	06	20
Office work	04	05	03	05	17
Vendors & Tailors	09	08	08	06	31
Rickshaw puller	03	05	03	03	14
Student	01	01	00	00	02

Socio-economic status was determined according to Kuppaswami's socio-economic scale. Majority of the patients (138) belonged to the low income group with a yearly income of less than Rs.

40,000, 52 patients were from medium income group (yearly income of Rs. 40,000–80,000), 12 patients were from high income group (yearly income of Rs. >80,000). In Fluoxetine group, 38 patients belonged to low income, 15 patients belonged to medium income group and 05 patients belonged to high income group. In Sertraline group, 41 patients belonged to low income group, 11 patients belonged to medium income group and 02 patients belonged to high income group. In Amitriptyline group, 30 patients belonged to low income group, 13 patients belonged to medium income group and 03 patients belonged to high income group.

In Desvenlafaxine group, 29 patients belonged to low income group, 13 patients belonged to medium income group and 02 patients belonged to high income group. Low income group was most common income group founds in all treatment groups.

It was observed that out of 202 patients, 178 patients had irregular sleep, while 24 had regular sleep. Appetite was irregular in 165 patients and regular in 37 patients. 45 patients (22.3%) were addicted to smoking, 27 patients (13.4%) were addicted to alcohol while 17 (8.4%) were addicted to both smoking and alcohol. 168 patients were married and 34 patients were unmarried. Menstrual history was normal in 62 female patients and irregular in 23 patients. In general, the presenting complaints were depressed mood, loss of interest, loss of weight, lack of concentration, fatigue, insomnia, anxiety, guilt, somatic symptoms and suicidal tendency. Common presenting features of study participants are shown in table 2. Presenting clinical features in different treatment groups were depicted in table 3.

Table 2: Clinical features of study participants

Symptoms	Number of patients (n=202)
Depressed mood	190 (94.1)
Loss of interest	176 (87.1)
Anxiety	158 (78.2)
Insomnia	158 (78.2)
Fatigue	135 (66.8)
Lack of concentration	133 (65.8)
Somatic symptoms	118 (58.4)
Guilt	114 (56.4)
Suicidal tendency	55 (27.2)

Table 3: Common symptoms in patients of major depression in different antidepressant treatment groups. (Values are expressed as percentage)

Group	Fluoxetine	Sertraline	Amitriptyline	Desvenlafaxine
Depressed mood	95	94	94	93
Loss of interest	91	83	87	86
Anxiety	90	80	70	81
Insomnia	83	78	74	77
Fatigue	74	57	65	70
Lack of concentration	78	70	57	55
Somatic symptoms	60	61	48	64
Guilt	71	54	52	45
Suicidal tendency	22	26	37	25

Past history of tuberculosis was present in 17 patients (6 patients in Fluoxetine group, 4 patients in Sertraline group, 3 patients in Amitriptyline group and 4 patients in Desvenlafaxine group). Diabetes mellitus was found in 16 patients (Fluoxetine group), 12 patients (Sertraline group), 11 patients (Amitriptyline group) and 07 patients (Desvenlafaxine group). Hypertension was found in 21 patients (Fluoxetine group), 16 patients (Sertraline group), 13 patients (Amitriptyline group) and 05 patients (Desvenlafaxine group). Concomitant hypertension and diabetes mellitus were found in 7 patients (Fluoxetine group), 8 patients (Sertraline group), 8 patients (Amitriptyline group) and 04 patients (Desvenlafaxine group).

78% of patients (n=202) were prescribed the antidepressant drugs by their generic name, while 22% of patients were prescribed by their brand name. All patients who received Fluoxetine, Sertraline, Amitriptyline were prescribed by their generic name, while patients who received Desvenlafaxine were prescribed by their brand name. All four antidepressant drugs were administered by oral route. Prescribed dose of Fluoxetine was 10 to 20 mg once a day in a morning, dose of Sertraline was 50-200 mg once a day, Amitriptyline was prescribed at a dose of

25 to 50 mg once or twice a day and Desvenlafaxine was prescribed at a dose of 50-100 mg once a day.

HDRS and MADRS score were recorded at baseline (Table 4). The values are expressed as mean \pm SEM. When mean baseline HDRS and MADRS score were compared between four treatment groups by applying one way-ANOVA test, no significant difference was found, hence all four treatment groups were comparable in terms of severity of depression.

Table 4: Comparison of baseline HDRS and MADRS score among four treatment groups (Values are expressed as mean \pm SEM)

Group	Fluoxetine (n=58)	Sertraline (n=54)	Amitriptyline (n=46)	Desvenlafaxine (n=44)
HDRS Scale	25.43 \pm 1.66	24.30 \pm 1.18	26.17 \pm 1.66	25.23 \pm 1.89
MADRS Scale	35.34 \pm 2.84	34.74 \pm 2.84	35.48 \pm 2.71	35.50 \pm 3.20

Discussion: Depression is a common mental disorder, characterized by sadness, loss of interest or pleasure, feelings of guilt or low self-worth, disturbed sleep or appetite, feelings of tiredness, and poor concentration.⁹ Although, depression is the leading cause of disability for both males and females, the burden of depression is 50% higher in females than in males.¹⁰ The average lifetime prevalence estimates of DSM-IV Major depressive episode were ranging from 11.1% to 14.6%.¹¹ In India 3-4% of the total population suffers from mental and behavioral disorders, of which, 7-10% suffer from depressive disorders.¹²

We have also observed that the large majority of patients in our study were more than 40 years of age (76.73%), this supports the view that prevalence of depression increases with age.¹³ Ageing is a normal process which is associated with physical, social, and psychological changes.¹⁴ As the age advances, there is increased morbidity and functional loss. Various life events experienced by the elderly population can greatly impact their psychological status, making them more prone to depression.^{15,16} Several Indian studies have identified the prevalence of depression from 6% to 62% in India.^{17,18}

Papadopoulos et al. 2005 showed no significant relationship between age and prevalence of depression.¹⁹ While many researchers like Sengupta and Benjamin 2015, Swarnalatha N 2013, Barua *et al.* 2010, Rajkumar *et al.* 2009 and Jain *et al.* 2007 had reported similar risk of depression with increasing age.²⁰⁻²⁴ A systematic review reported a median prevalence of 21.9% (IQR, 11.6–31.1%) for depression among the elderly in India.²⁵ Living alone, stressful life events, lack of social support systems, recent loss of a loved one, lower socioeconomic status and presence of co-morbid medical illnesses are some of the risk factors for depression in the elderly.

In our study a total of 109 (54%) patients were women, while the number of men patients was 93 (46%). According to WHO findings in 2017, Depression is more common among females (5.1% vs 3.6%) with a peak in the 55–74 year age group in both sexes.²⁶ A higher prevalence of depression among women and working age adults (aged 20–69 years) has been consistently reported by Indian studies.²⁷⁻³⁰ Several reasons are attributed to higher rates among women – biological and hormonal factors are found to be playing a greater role amidst a wide array of social and economic factors. Findings from NMHS have shown consistently higher rates for females across all age groups and among those residing in urban metros as compared to their counterparts. NMHS also reported a glaring differential in household income for depression with the prevalence of current depression in the lowest income quintile group (3.4%) being almost twice the prevalence in the highest 5 income quintile population (1.9%).

In our study 34% of patients were found illiterate. Similar results were found in studies conducted by Jonas JB et al 2014 (34.5%) & Poongothai S, et al 2009 (25.6%) of illiterate patients.^{31,32} Illiteracy results into a reduced level of self confidence, low self esteem, low income, poor employment and increased dependence on others for various reasons and hence depression. Lack of education often leads to lack of financial support and loss of social and psychological benefits of employment.³³

Majority of the patients (68.3%) in our study belonged to the low income group with a yearly income of less than Rs. 40,000. This is consistent with western studies, where people in the lower economic status were reported to be more

depressed compared to those in the middle and high income status.³⁴ Our data showed that there was an inverse relationship in prevalence of depression with income and education. One reason is that our study has been conducted in a government hospital where treatment is given free of cost or at a very low price. This attracts a large number of patients belonging to low socioeconomic status. Depression is associated with poverty in a vicious cycle. Depression often results in impaired functioning, which has an impact on all aspects of an individual's life and family affecting multiple areas of education, marriage, work and social life. These in turn lead to loss of productivity, increased health care costs and significant emotional suffering. People with depression are also unable to access quality health care due to increasing costs. It is projected to be the second leading cause of disease burden globally and third leading cause of disease burden in LMICs by 2030.³⁵ In LMICs, more than 80% of YLDs (non-fatal disease burden) were attributed to depression.³⁶

A total of 88.12% patients had irregularity in sleep while 81.68% patients were reported to have irregular appetite. It has been reported that patients of depression can suffer from insomnia, very early morning awakenings (getting up much earlier than the usual time), which may result into excessive day time sleepiness, fatigue, and poor sleep quality. In a study conducted by Jain RK, et al, 2007, also observed that people who are not satisfied with their sleep had greater chances to suffer from depression.³⁷ This finding shows that depression can affect the sleep and vice-versa.

45 patients (22.3%) were addicted to smoking, 27 patients (13.4%) were addicted to alcohol while 17 (8.4%) were addicted to both smoking and alcohol. In Indian study conducted by Jonas JB, et al., 2014, 18.9% patients were found addicted to smoking and 23% patient were addicted to alcohol.³¹ Prevalence of alcohol is lower as compare to other study because of drinking alcohol is prohibited in Gujarat. Depressive symptoms can precede, follow, or co-occur with substance abuse problems. According to a study conducted by Nunes, et al, 2006, substance use disorders relate to depressive symptoms or a depressive disorder in a variety of ways.³⁸ Having a substance use disorder increases the risk of experiencing depressive symptoms or a depressive disorder. Similarly, having a

depressive disorder increases risk of substance use disorder.

Majority of (78%) of patients (n=202) were prescribed the antidepressant drugs by their generic name, while 22% of patients were prescribed by their brand name. All patients who received Fluoxetine, Sertraline, and Amitriptyline were prescribed by their generic name, while patients who received Desvenlafaxine were prescribed by their brand name. All four antidepressant drugs were administered by oral route. Prescribed dose of Fluoxetine was 10 to 20 mg once a day in a morning, dose of sertraline was 50-200 mg once a day, Amitriptyline was prescribed at a dose of 25 to 50 mg once or twice a day and Desvenlafaxine was prescribed at a dose of 50-100 mg once a day. In our study all four drugs were given by standard prescribed dose and commonly prescribed route, frequency according to their bioavailability and t_{1/2}. Similar dose ranges given in O'Donnell JM, et al, 2011.³⁹

HDRS and MADRS score were recorded in all study participants. Baseline HDRS score for all the four study groups were quite similar to that reported in other studies.^{40,41} HDRS score of >17 considered as severe depression and our study included severe depressive patients. Similar results were obtained while comparing the MADRS scores of present study groups and previous studies.^{40, 42-44}

Conclusion: To summarize and conclude, MDD was found more in female as compared to male. MDD was found more in elderly age group. Majority of patients in this study belonged to the low socio-economic group. Around 50% of the study participants were illiterate. Fluoxetine, Sertraline, Amitriptyline and Desvenlafaxine were the prescribed antidepressant agents in the study participants. But age, sex, occupation, socio-economic level and presenting clinical features were found to be having no correlation with the selection of the antidepressant agent.

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