



A Cross-sectional, Multicenter, Observational Study to Assess the Safety and Usage Pattern of Antidepressants in the Management of Indian Patients with Major Depressive Disorder

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Abstract

Background: Major depressive disorder (MDD) is a leading cause of disability worldwide, with rising prevalence. Antidepressants (ADs) remain the cornerstone of treatment for depression and anxiety. However, data on AD prescribing patterns in India are limited, which is essential for optimizing treatment strategies.

Objective/Aim: To evaluate the usage and safety patterns of commonly prescribed ADs (escitalopram, sertraline, and vortioxetine) in Indian patients with MDD.

Methods: This retrospective, observational study analyzed data of 3,321 Indian patients having MDD. Data were collected by 306 psychiatrists and clinicians using structured DCFs, and analyses were performed using SPSS (v29.0.1.0) and Microsoft Excel 2019. Ethics approval was obtained before study initiation.

Results: The mean (SD) age of the study population was 44.0 (12.9) years, with males comprising 64.8% of the cohort. Most patients (70.6%) reported no family history of MDD. Anxiety was the most common psychiatric comorbidity (59.0%), while diabetes (22.9%) was the most frequent non-psychiatric comorbidity. Among antidepressants, escitalopram was the most prescribed agent (50.6%), followed by vortioxetine (28.1%) and sertraline (21.0%). Clonazepam was the most frequently co-prescribed benzodiazepine (36.0%). Escitalopram was commonly initiated at 10 mg once daily (80.0%), predominantly as monotherapy (55.2%), with treatment duration of 2–6 months (39.7%). Nausea (24.5%) and dizziness (13.9%) were the most reported adverse events.

Conclusion: Escitalopram emerged as the preferred AD, with frequent clonazepam co-prescription for comorbid anxiety. These patterns reflect common clinical practice and highlight the need for individualized treatment strategies in MDD management.

INTRODUCTION

Major Depressive Disorder (MDD), as defined by DSM-5 and ICD-10/11, is characterized by a prolonged episode of depressed mood or loss of interest, accompanied by symptoms such as changes in appetite or weight, sleep distur-

bances, fatigue,^{1,2} feelings of worthlessness, impaired concentration, and recurrent thoughts of death or suicide. Globally, depression affects more than 300 million people and is recognized as a leading contributor to disability, with the World Health Organization ranking it the third highest cause of global disease burden in 2018 and projecting it to become the leading cause by 2030. Vulnerable populations such as women, elderly, and adolescents show a particularly high risk, influenced by genetic, psychological, and socio-environmental factors.³ In India, the National Mental Health Survey (NMHS) 2015–2016, covering over 34,000 adults across 12 states, reported a lifetime prevalence of depressive disorders of 5.25% and a current prevalence of 2.68%. Contributing factors include urbanization, lifestyle changes, and rising comorbid non-communicable diseases. The disability burden is considerable, with most affected individuals experiencing impairment in work, family, or social functioning, while nearly 80% remain untreated, reflecting significant gaps between prevalence and effective clinical management.⁴ Comorbid conditions are common in MDD, with frequent co-occurrence of anxiety disorders, cardiovascular disease, diabetes, and other chronic illnesses.⁵ Such multimorbidity often necessitates polypharmacy, which increases the risk of drug-drug interactions, adverse events, and reduced adherence due to complex treatment regimens and side effects.^{6,7} A wide range of antidepressant classes are available, including tricyclic antidepressants (TCAs), monoamine oxidase inhibitors (MAOIs), selective serotonin reuptake inhibitors (SSRIs), serotonin–noradrenaline reuptake inhibitors (SNRIs), and other newer agents.^{8,9} Globally, the growth in antidepressant prescriptions has been driven largely by the increasing use of SSRIs and newer drugs. However, challenges persist, including variability in prescribing practices, issues of underuse or overuse, poor adherence, and safety concerns.^{10,11} Despite the clinical importance of antidepressant therapy, real-world evidence on prescribing patterns and safety in India remains limited, underscoring the need for systematic evaluation in local practice settings. The aim of this study was to evaluate the safety and utility patterns of the antidepressants (vortioxetine, escitalopram, and sertraline) in patients having MDD.

MATERIAL AND METHODS

Study Design

This was a non-interventional, retrospective, observational study conducted across 306 outpatient sites in India between January 2023 and January 2024. Male and female patients with a confirmed diagnosis of major depressive disorder (MDD) who had received treatment with at least one of the antidepressants (vortioxetine, escitalopram, or sertraline) were included in the study.

The study protocol was reviewed and approved by the Sangini Hospital Ethics Committee, Ahmedabad, Gujarat, India (Registration no: ECR/147/Inst/GJ/2013/RR-19 and IORG0007258). The study was conducted in accordance with the principles outlined in the Declaration of Helsinki (2013 revision), the Indian Council of Medical Research (ICMR) National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017), and all applicable regulatory requirements.

Study Objective

The primary objective of the study was to evaluate the safety and usage pattern of commonly used antidepressants with a focus on vortioxetine, escitalopram, and sertraline in the management of MDD in Indian patients.

The secondary objective of the study was to understand and document the prevalence and medications used in other co-morbid conditions along with depression in Indian patients.

Study Procedures

Data were first extracted from patient medical records and transcribed into standardized data collection forms (DCFs) by the clinicians and psychiatrists. The completed DCFs were cross-verified against the original medical records to ensure accuracy. Following this, the verified data were entered into the excel. A second round of quality checks was performed by comparing the entered data with the respected DCFs to confirm completeness and consistency before statistical analysis. Incomplete data or partially filled DCFs were excluded in the analysis.



Data Collection

Patients' demographic data including their age, gender, height, body weight, marital status, smoking, and alcohol history were captured. Additionally, family history along with the duration of depression and the risk factors were noted with the psychiatric and non-psychiatric comorbidities, if any.

Antidepressant drug details were captured which included the antidepressant name, dose, and its frequency with duration and type of therapy and co-prescribed medicines, if any. Lastly, the safety profile was documented based on past medical records.

Sample Size Calculation

No formal sample size calculation was performed, being a real-world, retrospective observational study, sample size was carried out pragmatically,¹² based on the number of eligible patient medical records available during the study period (January 2023–January 2024), a total of 3,500 patient records were analysed across 306 outpatient sites in India.

Statistical Analysis

Statistical analyses were performed using SPSS software (version 29.0.1.0; IBM, USA) and Microsoft Excel 2019. Data from subjects who met eligibility criteria and had complete records were included in the analysis. Descriptive statistics were used to summarize the data. Categorical variables were presented as frequencies and percentages, while continuous variables were summarized using mean and standard deviation (SD).

RESULTS

A total of 3,500 patient records were screened for eligibility. Of these, 179 records were excluded due to incomplete data. Consequently, complete case analysis was performed, and 3,321 patient records were included in the final analysis set. The study process flow is depicted in Figure 1.

Demographic Distribution

The demographic distribution indicated that the male-to-female ratio was nearly 2:1 in the study.

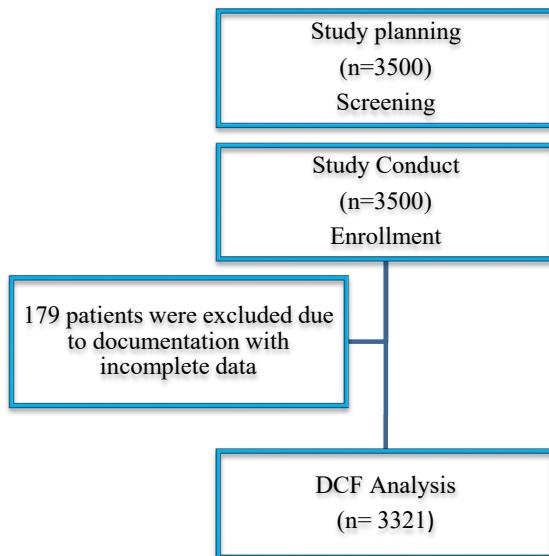


Figure 1: Study Process Flow (CONSORT diagram)

The mean age of the study population was 44 (12.9) years. Almost 74% of the patients belonged to the age group 30–60 years. A summary of demographic distribution is shown in Table 1.

Antidepressant Usage Pattern

Of the total study population, 1682 (50.6%) patients were prescribed escitalopram, while 932 (28.1%), and 697 (21.0%) patients were prescribed vortioxetine and sertraline, respectively. Most common starting and maintenance dose for escitalopram was 10mg, for vortioxetine 5 and 10mg, and for sertraline 50 and 25mg, respectively. For vortioxetine and sertraline, patients were down titrated to a lower dose when it came to maintenance.

Most of the subjects (2658 (80%)) were managed with a once-daily dose. Of the total study population, 1320 (39.7%) received antidepressant therapy for the duration of 2–6 months, and 886 (26.7%) received it for 6–12 months.

The trend for monotherapy was slightly higher, at 55%, compared to the combination therapy. The antidepressant usage pattern is depicted in Figure 2.

Drugs Co-prescribed with Antidepressants

Clonazepam was the most commonly co-prescribed drug. It was present in 1195 (36%) of prescriptions. A

Table 1: Demographic distribution

Characteristic		N
Total Study Population		3321 (100%)
Gender	Female	1168 (35.2%)
	Male	2153 (64.8%)
Age Group (years)	<30	446 (13.4%)
	30-44	1392 (41.9%)
	45-60	1075 (32.4%)
	>60	408 (12.3%)
Age (years)	Mean (SD)	44.0(12.9)
Weight (kg)	Mean (SD)	67.0(11.3)
Height (cm)	Mean (SD)	163.4(8.9)

summary of the distribution of co-prescribed drugs is mentioned in Table 2.

Patient Characteristics

A family history of depression was seen in 977 (29.4%) patients. Trauma or negative life events (1755 (52.8%)) emerged as a common risk factor. The duration of depression in more than 85% of patients was less than 3 years. Rural and urban settings of patients

showed a similar distribution of prevalence. Most patients were married (2528 (76.2%)). A summary of the patient's characteristics is mentioned in Table 3.

Prevalence of Co-morbid Conditions

Anxiety (59%) was noted as the most common psychiatric comorbidity amongst the study population followed by schizophrenia (11.1%), and substance abuse (10.1%). Lifestyle diseases such as diabetes (22.9%) and hypertension (19.7%) were the commonest non-psychiatric comorbidities. A summary of the distribution of co-morbid conditions is presented in Table 4.

Safety Profile

Nausea (814 (24.5%)) was the most commonly reported adverse reaction followed by dizziness (462 (13.9%), and vomiting (422 (12.7%)).

DISCUSSION

This large-scale, retrospective pharmacoepidemiologic study assessed the safety and usage patterns

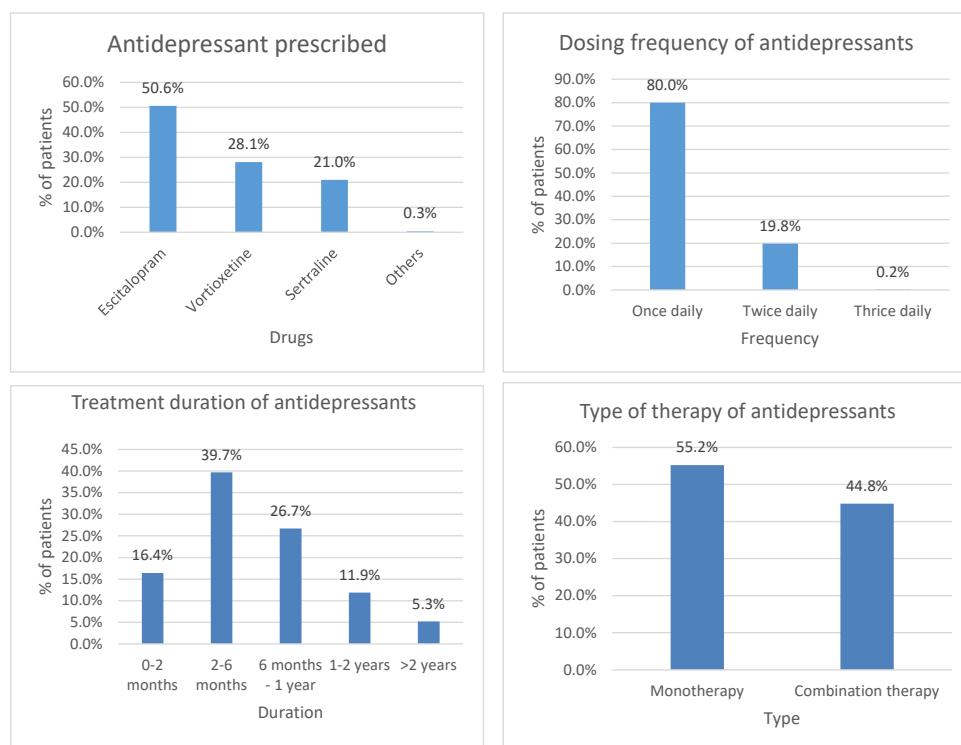


Figure 2: Usage pattern of Antidepressants

Table 2: Summary of co-prescribed drugs

Co-prescribed Drugs		N	%
If combination therapy, commonly combined with	Clonazepam	1195	36.0%
	Alprazolam	142	4.3%
	Etizolam	106	3.2%
	Diazepam	96	2.9%
	Tofisopam	84	2.5%
	Others	57	1.7%

of antidepressants, with a focus on escitalopram, vortioxetine, and sertraline, for treating MDD within the Indian population.

In our study, the prevalence rate of MDD was higher in males (64.8%) than in female (35.2%). Similar results were found in study done by Vishal et al, Mohamand et al and Ghosh et al, with the prevalence of depression in males being 55.63%, 51.8% and 54.67% and in females being 44.36%, 48.2%, and 45.33% respectively.¹³⁻¹⁵

In the present study, MDD prevalence was highest among individuals aged 30–60 years, followed by those <30 years, and lowest in those >60 years. A population-based Indian study by Arvind et al. similarly reported the highest prevalence in the 40–59-year age group, followed by those >65 years, and the lowest in individuals <30 years.⁴ In contrast, global data generally indicate the peak burden in younger adults (<30 years), with prevalence declining with age. This variation may reflect sociocultural factors, delayed diagnosis in younger individuals, and greater utilization of healthcare services among midlife adults, along with increased psychosocial stressors and comorbidities during midlife.¹⁶⁻¹⁷

In our study, family history of depression was reported in 29.4% of patients. This aligns with recent genetic studies showing MDD heritability of about 30–59%, underscoring the genetic contribution and the relevance of family history in clinical populations.¹⁸ Another recent meta-analysis of genetic polymorphism studies estimated heritability at about 37% (95% CI 31-42%) based on twin and family data.¹⁹ Among risk factors, trauma or negative life events were most frequent (52.8%), consistent with Wang's review highlighting stressful life events such as abuse, bereavement, or divorce as significant

Table 3: Patient characteristics

Characteristic		N	%
Family History of Depression	Yes	977	29.4%
	No	2344	70.6%
	Trauma/Negative life event	1755	52.8%
	Genetics	690	20.8%
Risk Factors	Health Condition	652	19.6%
	Age	494	14.9%
	Gender	442	13.3%
	Others	126	3.8%
	0-1 years	1368	41.2%
Duration of Depression	1-3 years	1498	45.1%
	3-5 years	363	10.9%
	>5 years	92	2.8%
Residence	Rural	1541	46.4%
	Urban	1780	53.6%
	Unmarried	529	15.9%
Marital Status	Married	2528	76.2%
	Widowed	157	4.7%
	Divorced/ Separated	107	3.2%
Smoking	Yes	1356	40.8%
	No	1965	59.2%
Alcoholic	Yes	1280	38.5%
	No	2041	61.5%

triggers for depressive episodes.²⁰ Urban residency was slightly more common (53.6%), aligning with meta-analyses showing higher depression prevalence in urban areas due to psychosocial stressors.²¹ Additionally, smoking (40.8%) and alcohol use (38.5%) were notable, which agrees with systematic reviews reporting strong associations between substance use and depression.²² These findings underscore the multifactorial nature of MDD, influenced by genetic, environmental, and lifestyle factors, and are broadly consistent with patterns observed in Indian and global studies. Treatment duration in our study showed that 39.7% of patients were on antidepressants for 2–6 months, while 26.7% continued for 6–12

Table 4: A summary of the distribution of co-morbid conditions

Co-morbid conditions		N	%
Psychiatric Comorbidity	Anxiety	1960	59.0%
	Schizophrenia	369	11.1%
	Substance Abuse	336	10.1%
	Others	35	1.1%
	None	882	26.6%
Non-Psychiatric Comorbidity	Diabetes	760	22.9%
	Hypertension	655	19.7%
	Thyroid Disorder	344	10.4%
	Dyslipidemia	318	9.6%
	Asthma	239	7.2%
	Others	59	1.8%

months. This is consistent with Indian Council of Medical Research (ICMR) guidelines recommending continuation of therapy for 6–9 months after achieving remission to prevent relapse.²³

Among the prescriptions analysed, escitalopram (50.6%) emerged as the most prescribed drug for major depressive disorder (MDD), followed by vortioxetine (28.1%) and sertraline (21%). This finding aligns with previous Indian studies highlighting the dominance of selective serotonin reuptake inhibitors (SSRIs) in clinical practice. Kulkarni et al. reported that SSRIs constituted 32.18% of prescriptions, making them the most commonly prescribed class, followed by atypical antidepressants (0.64%). Similarly, a study from North India observed that SSRIs were the preferred class (61.26%), with escitalopram (58.4%) being the most frequently prescribed agent, followed by sertraline (7%).^{13,24} The Indian Psychiatric Society (IPS) multicentric study further corroborates these findings, reporting that escitalopram accounted for 40% of antidepressant prescriptions, followed by sertraline (17.6%) and fluoxetine (16.3%). Overall, SSRIs represented 79.2% of all prescriptions, underscoring their role as first-line therapy in India.²⁵ Recent expert opinion surveys also reinforce the preference for escitalopram, with 87% of psychiatrists favouring it over other SSRIs due to its efficacy and tolerability profile. Approximately 64% of respondents reported significant improvement in

50–75% of patients treated with escitalopram, and nearly half indicated that remission typically occurs within 8 weeks.²⁶ Emerging evidence on vortioxetine suggests its growing role in Indian practice. A randomized comparative study demonstrated that vortioxetine is as effective as escitalopram in reducing depressive symptoms, with a potentially faster onset of action and a lower incidence of sexual dysfunction and weight gain, which may influence future prescribing trends.²⁷

In our study, escitalopram was most often prescribed at 10 mg for both initiation and maintenance, consistent with guideline-recommended dosing. Vortioxetine was commonly started at 5 mg and maintained at 10 mg, while sertraline was initiated at 50 mg and maintained at 25 mg, possibly reflecting individualized titration for tolerability.^{28–29} Similar dosing patterns have been reported in Indian and global literature, where SSRIs and vortioxetine are typically administered once daily due to favorable pharmacokinetics.

Regarding dosing frequency, 80% of patients in our cohort received once-daily administration, which is in line with the pharmacokinetic profiles of SSRIs and vortioxetine that allow for single daily dosing. Comparable findings have been reported in Indian studies, where once-daily dosing predominates due to improved adherence and convenience.^{10,30}

In terms of therapy type, 55.2% of patients received monotherapy, while 44.8% were on combination therapy. Although monotherapy remains the first-line approach, combination therapy is increasingly used in clinical practice for partial responders or severe cases. Evidence from a meta-analysis and clinical study indicates that combination therapy can provide superior efficacy compared to monotherapy without significantly increasing dropout rates, particularly when combining agents with complementary mechanisms.^{31,32}

In our study, the most common adverse effects were nausea (24.5%) and dizziness (13.9%). These findings are consistent with published evidence indicating that gastrointestinal symptoms, particularly nausea, are among the most frequently reported side effects of SSRIs and vortioxetine. Uher et al. (2009) reported that nausea is the most common early-onset adverse effect of antidepressants, especially SSRIs, often occurring within the

first weeks of treatment and typically resolving over time.³³ A cross-sectional study on SSRIs (sertraline, escitalopram, fluoxetine) found dizziness and light-headedness among the common adverse effects, particularly with escitalopram.³⁴ For vortioxetine, clinical trial data confirm that nausea is the most frequent adverse event, followed by dizziness and headache, with most events occurring within the first month of therapy.^{35,36}

In our study, anxiety (59.0%) emerged as the most frequent psychiatric comorbidity in MDD, which is consistent with recent evidence showing that 50–75% of patients with MDD meet DSM-5 criteria for anxious depression, and this comorbidity is associated with poorer outcomes and delayed remission.³⁷ Among non-psychiatric comorbidities, diabetes (22.9%) was most common, aligning with recent meta-analyses confirming a bidirectional association between depression and type 2 diabetes.³⁸ Hypertension (19.7%) and dyslipidemia (9.6%) were also notable, reflecting the metabolic burden frequently observed in MDD and supported by recent studies linking depression with metabolic syndrome and cardiovascular risk factors.³⁹ Thyroid disorders (10.4%) in our cohort are comparable to recent findings showing a significant association between depression and thyroid dysfunction, particularly hypothyroidism and subclinical hypothyroidism.⁴⁰

CONCLUSION

This study highlights current antidepressant prescribing trends in India, with escitalopram as the preferred agent and frequent co-prescription of clonazepam for managing comorbid anxiety. These findings reflect a common clinical practice of short-term benzodiazepine use alongside antidepressants for symptomatic relief, while underscoring the importance of individualized treatment strategies in MDD management.

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CONFLICT OF INTEREST

Mr. Yakshdeep Dave, Dr. Zahraan Qureshi and Mr. Girish Kulkarni declares employment from Torrent Pharmaceuticals Ltd., Ahmedabad. All other authors declares no conflict of interest.

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