# An observational study to evaluate the awareness of drug treatment, prescription pattern, adverse drug reactions, and adherence in patients of major depressive disorder

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Aims: Due to the paucity of studies in and out of India that dealt with treatment awareness of major Abstract depressive disorder (MDD), we decided to assess the awareness of MDD patients, and since adherence and awareness are linked to each other, we assessed adherence too. Prescription pattern studies identify changes in prescriptions due to poor initial response or adverse drug reactions (ADRs), which may result in dose reduction or switching medications and delay remission. Therefore, the study assessed the ADR pattern. Methodology: A cross-sectional questionnaire-based study was carried out on 200 MDD patients with treatment records for at least 3 months after getting approval from the Institutional Ethics Committee and consent from the patients. The data obtained were entered in Microsoft Excel and analyzed using descriptive statistics. **Results:** The mean age was  $44.65 \pm 12.02$  years, and females were 70%. Maximum patients (98%) were aware of the consequence of stopping the drugs suddenly, and only 12.5% were aware of the onset of response to treatment. Escitalopram was the most common antidepressant prescribed (43.77%), and 67 ADRs out of 136 were attributable to it. Weakness and fatigue were the most common ADRs. The majority (97) of the ADRs were possibly related to antidepressants, and 65% of patients showed optimal adherence to medications. Conclusions: This study sheds light on the treatment awareness and adherence of MDD patients in India and highlights the need for educating patients about treatment response. It also emphasizes the importance of monitoring ADRs and adjusting prescription patterns accordingly to improve treatment outcomes.

Keywords: Adherence, awareness, escitalopram, major depressive disorder

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### **INTRODUCTION**

Major depressive disorder (MDD) is a common illness that severely limits psychosocial functioning and diminishes the quality of life. It is characterized by  $\geq 2$  weeks of

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depressed mood or loss of interest, associated with many other symptoms such as disturbed sleep, decrease in appetite and libido, psychomotor changes, reduced concentration, and excessive guilt. It is insidious and often

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recurrent.<sup>[1]</sup> Approximately 280 million people in the world have depression.<sup>[2]</sup> The WHO 2015 report suggested that 4.5% of the Indians were affected by depressive disorders.<sup>[3]</sup>

In 2008, the WHO predicted that major depression would become the leading cause of disease burden by 2030, ranking third at that time.<sup>[4]</sup> The 12-month prevalence of MDD is approximately 6%, varying across countries.<sup>[5]</sup> Depression is more common in women, with peaks in the prevalence occurring in the 2<sup>nd</sup> and 3<sup>rd</sup> decades of life and a smaller peak in the 5<sup>th</sup> and 6<sup>th</sup> decades.<sup>[6-8]</sup>

Despite the effectiveness of antidepressants, medication adherence in depressed patients is often poor, with rates ranging from 30% to 97%.<sup>[9]</sup> Optimal adherence is associated with positive outcomes regardless of the antidepressant used, and lack of treatment awareness is a predictor of poor adherence.<sup>[10]</sup> Therefore, we investigated treatment awareness levels in MDD patients. While awareness studies have been conducted for conditions such as hypertension, diabetes, and anemia,<sup>[11-13]</sup> there are limited published studies globally and in India that explore treatment awareness in MDD patients.<sup>[14,15]</sup>

Antidepressant prescribing patterns have shifted in recent years, with selective serotonin reuptake inhibitors (SSRIs) and novel antidepressants replacing tricyclic antidepressants and monoamine oxidase inhibitors. It is important to monitor changes in prescriptions when initial treatment fails or when drugs cause side effects. The WHO employs three standardized core indicators to assess prescribing patterns: prescribing, patient care, and health facility indicators.<sup>[16]</sup>

The primary objective of managing MDD is remission of depressive symptoms while minimizing complications and risk of relapse. Antidepressants take several weeks to achieve full efficacy; however, adverse effects can occur much sooner, leading to noncompliance. Adverse drug reactions (ADRs) may require dose adjustments or switching to different medications, which can delay remission.<sup>[17]</sup> Therefore, this study evaluates ADRs in MDD patients at the Psychiatry Outpatient Department (OPD) of K. E. M Hospital, Mumbai.

Considering these findings, our study aimed to comprehensively evaluate four factors in the same study setting: drug treatment awareness, prescription patterns, ADRs, and medication adherence in depressed patients.

### **METHODOLOGY**

### Study design, site, and duration

This study was a cross-sectional, observational, single-center, and questionnaire-based study carried out by the Department of Pharmacology and Therapeutics of Seth G. S. Medical College, in collaboration with the Psychiatry Department situated at K. E. M. Hospital, Mumbai. The study was carried out between June 2021 and December 2022.

## **Ethical considerations**

The study obtained approval from the Institutional Ethics Committee under the number EC/24/2021. It was also registered with the Clinical Trials Registry of India (REF/2021/05/043392) before enrolling patients.

### Sample size

A total of 200 patients were selected using the duration-based sampling technique.

### Selection criteria

### Inclusion criteria

- Patients attending psychiatry OPD
- Both sexes, aged between 18 and 65 years
- Established diagnosis of MDD according to the Diagnostic and Statistical Manual of Mental Disorders-V criteria
- Treatment records available for at least 3 months.

### Exclusion criteria

- Patients admitted to the psychiatry inpatient department and emergency department
- Newly diagnosed and treatment-naive patients
- Patients with a history of substance dependence or abuse at the current visit
- Patients with neurological disorders (dementia, delirium, and cognitive disorders), seizure disorders, sensory impairment, or other psychiatric disorders such as mood and anxiety disorders
- Critically ill patients requiring urgent medical attention
- Severely agitated patients or those with active suicidal ideation
- Patients unwilling to participate in the study.

# Designing of case record form and drug awareness questionnaire

Case record form included patient demographic details such as age, sex, literacy level, socioeconomic status (Modified Kuppuswamy Scale), disease duration, comorbid conditions, and current prescription details (generic name, brand name, dosage form, dose, frequency, duration, follow-up instructions, and average consultation time). Each recruited patient was considered as an encounter.

The drug awareness questionnaire consisted of seven domains and 17 items, covering various aspects of drug knowledge. The domains included current prescriptions, factors affecting drugs and doses, dosing schedule importance, preserving the past prescriptions, follow-up, side effects, and treatment response onset. The questionnaire underwent validation by eight experts, achieving a content validity ratio of 0.83. The questionnaire was administered by a single investigator.

### Assessment of adverse drug reactions and adherence

The WHO Uppsala Monitoring Center (UMC) Causality Assessment Scale was used to determine the causality of ADRs. The severity of ADRs was evaluated using the Hartwig-Siegel Scale, and preventability was assessed with the Schumock and Thornton Scale. Adherence was measured using the Medication Adherence Rating Scale, with scores interpreted as optimal adherence ( $\geq$ 7), suboptimal adherence (4–6), and poor adherence ( $\leq$ 3) out of 10.

### Data analysis

Descriptive statistics were applied using Microsoft Excel. Statistical analysis was performed using SPSS Software (version 26) (IBM Corp, Armonk, New York, USA). Pearson's correlation test was utilized for correlation analysis to examine the relationship between patient demographic factors (age, gender, socioeconomic status, and duration of disease) and drug awareness scores.

### Table 1: Drug awareness questionnaire responses and scores

### RESULTS

The number of females (140, 70%) that participated in the study was greater compared to males (60, 30%). The mean age was  $44.65 \pm 12.02$  years. According to Modified Kuppuswamy scale,<sup>[18]</sup> majority patients belonged to upper-lower (85,42.5%) and lower-middle (58,29%) class, followed by (47, 23.5%) in upper middle, (6,3%) in upper class and (4,2%) in lower class. Patients with middle school education were (65, 32.5%), high school (48,24%), intermediate education (34,17%), graduation (20,10%), primary school education (17,8.5%), postgraduation (4,2%) & illiterate (12,6%). The median disease duration was 5 years (interquartile range: 2-11). The majority of patients were diagnosed with depression within the last 1-5 years (59, 29.5%), followed by a duration of 5-10 years (43, 21.5%),  $\leq 1$ year (40, 20%), 10-15 years (25, 12.5%), 15-20 years (20, 10%), and  $\geq 20$  years (13, 6.5%). Hypertension (32, 16%) was the most common physical comorbidity, followed by diabetes (24, 12%).

### Drug awareness questionnaire

The mean score of 200 patients who were administered the questionnaire was  $15.67 \pm 3.508$  (mean  $\pm$  standard deviation). Item-wise responses and domain-wise scores of the patients are portrayed in Table 1.

Serial number	Item	Domain-wise mean scores*	Awareness (n=200), n (%
Domain I	Current prescription domain	urrent prescription domain 1.72±0.843 (maximum score=4)	
1.1	The number of medicines prescribed	· · · · · · · · · · · · · · · · · · ·	76 (38)
1.2	Names of medicines prescribed		38 (19)
	Dose and dosing frequency of medicines prescribed		124 (62)
3	The reasons for which each of the medicines was prescribed		113 (56.5)
Oomain II	Factors affecting drugs and their doses	4.52±2.632 (maximum score=8)	
Ļ	Factors depending on the drugs severity of the disease		148 (74)
	Response to treatment		104 (52)
	Presence of other illnesses		102 (51)
	Intake of concurrent medications		48 (24)
5	Factors depending on doses of drugs severity of the disease		148 (74)
	Response to treatment		104 (52)
	Presence of other illnesses		102 (51)
	Intake of concurrent medications		48 (24)
omain III	Dosing schedule and its importance	2.20±0.645 (maximum score=4)	
	Dosing schedule		180 (90)
	Consequence of stopping the drug suddenly		196 (98)
	Skipping doses		69 (34.5)
	What is to be done if the patient skips a medication dose		93 (46.5)
omain IV	Importance of preserving the past prescriptions	0.96±0.200 (maximum score=1)	
0	Preserving the past prescriptions		184 (92)
omain V	Follow-up domain	4.84±1.519 (maximum score=6)	
1	Next follow-up		160 (80)
2	Keeping regular follow-ups with the consulting physician		192 (96)
3	Intake of concurrent medications		188 (94)
omain VI	Side effects domain	1.32±1.180 (maximum score=3)	
4	Occurrence of undesired side effects		66 (33)
5	Reporting side effects to the doctor		189 (94.5)
6	Need for separate treatment to manage side effects		117 (58.5)
omain VII	Onset of response to treatment domain	0.20±0.408 (maximum score=1)	. ,
7	Onset of response to treatment		25 (12.5)
	Overall questionnaire score	15.67±3.508 (maximum score=27)	

\*Minimum score is 0 for all domains

The correlation between patient's age and gender with drug awareness scores was not statistically significant. The patient's socioeconomic status had a weakly negative correlation (Pearson [r] = -0.36) with drug awareness scores, while the patient's duration of disease had a moderately positive correlation (Pearson [r] = 0.63) with the scores with Pearson correlation test.

### Prescription pattern analysis

Results of the WHO's prescribing indicators, patient care indicators, and health facility indicators have been summarized in Tables 2-4, respectively.

### Utilization of individual antidepressants

A total of 233 antidepressants were prescribed in 200 prescriptions. Among 233, only 92 (39.48%) antidepressants were prescribed from key drug list. Only amitriptyline and imipramine were present in the key drug list. Escitalopram (n = 102, 43.77%) was the most commonly prescribed antidepressant, followed by amitriptyline (n = 57, 24.46%) and imipramine (n = 35, 15.02%).

### Antidepressant fixed-dose combinations

Only six fixed-dose combinations (FDCs) were seen in the prescriptions. Escitalopram + olanzapine and clonazepam + escitalopram were seen in two prescriptions each. Fluoxetine + olanzapine, amitriptyline + chlordiazepoxide, clonazepam + propranolol, and pregabalin + methylcobalamin were seen in one prescription each.

# Antidepressant drug utilization in terms of prescribed daily dose/defined daily dose

The prescribed daily dose/defined daily dose ratio was calculated for all prescribed antidepressants as per the WHO criteria. It was the highest for desvenlafaxine and the lowest for clomipramine.

### Monotherapy versus polytherapy

One antidepressant was prescribed in 141 (70.5%) encounters. More than one antidepressant was prescribed in 59 (29.5%) encounters.

### Concomitant medications

Benzodiazepines were prescribed in 91 (45.5%) encounters; out of which clonazepam was most commonly prescribed. Drugs such as MVBC, FSFA, and calcium tablets were prescribed in (68, 34%) encounters. Pantoprazole was the most commonly prescribed proton-pump inhibitor (26 encounters). Antipsychotics like olanzapine were prescribed in five encounters.

### Adverse drug reaction analysis

ADRs that occurred within the last 3 months of the patient's current visit were recorded. A total of 136

### Table 2: WHO Prescribing Indicators

WHO prescribing indicators	Results
Average number of drugs per encounter	2.73±1.23
Average number of antidepressants per encounter	1.36±0.58
Percentage of drugs prescribed by generic name (%)	27
Percentage of drugs prescribed from the national	74.63
essential drugs list (%)	
Percentage of drugs prescribed from the WHO	70.22
essential drugs list (%)	

### **Table 3: Patient Care Indicators**

Patient care indicators	Results
Average consultation time	7 min 37 s
Patients' knowledge about medications	Percentage of patients who answered appropriately
Name of the medications (%)	19
Reasons why each medication written on the prescription is given (%)	56.5
Dose and dosing frequency (%)	62.5

#### **Table 4: Health Facility Indicators**

Health Facility indicators	Results
Availability of a copy of the formulary list	Yes
Availability of key drugs (%)	33.17

## Table 5: Prescribed daily dose/defined daily dose ratio for the prescribed antidepressant

Drug	ATC code	PDD (mg)	DDD (mg)	PDD/DDD (mg)
Escitalopram	N06AB10	12.72	10	1.2
Amitriptyline	N06AA09	51.05	75	0.68
Imipramine	N06AA02	79.42	100	0.79
Mirtazapine	N06AX11	15	30	0.5
Fluoxetine	N06AB03	28.57	20	1.42
Sertraline	N06AB06	78.84	50	1.57
Dosulepin	N06AA 16	75	150	0.5
Clomipramine	N06AA04	25	100	0.25
Desvenlafaxine	N06AX23	131.25	50	2.62
Paroxetine	N06AB05	25	20	1.25

PDD=Prescribed daily dose, DDD=Defined daily dose,

ATC=Anatomical Therapeutic Chemical Classification

ADRs were found in 41 (20.5%) out of 200 patients. Out of 136 ADRs, 67 were attributable to escitalopram, 24 each to amitriptyline and imipramine, 23 to fluoxetine, 14 to sertraline, and four to mirtazapine. Weakness and fatigue (n = 16) were the most commonly captured ADRs, followed by weight gain (n = 15) and dry mouth (n = 15).

As per the WHO UMC causality assessment scale, 97 ADRs were possibly, while 39 were probably related to the antidepressant medication. According to the Modified Hartwig and Siegel ADR severity assessment scale, all ADRs were of mild severity. According to the Schumock and Thornton Preventability Scale, all ADRs were nonpreventable.

### **Medication Adherence Rating Scale**

According to the Morisky Medication Adherence Rating Scale, 130 (65%) patients showed optimal adherence, while Perspectives in Clinical Research | Volume 15 | Issue 2 | April-June 2024 65 (32.5%) patients showed suboptimal adherence, and 5 (2.5%) patients showed poor adherence.

### DISCUSSION

Regarding patient demographics, most patients were female, consistent with studies in Brazil by Pitcairn *et al.*<sup>[19]</sup> and in Telangana by Laxmi and Mounika.<sup>[20]</sup> According to the Global Burden of Disease Study (1990–2017), depression is twice as common in females than males, potentially due to gender discrimination, violence, sexual abuse, antenatal and postnatal stress, and adverse sociocultural norms.<sup>[21]</sup> The average age of the patients was 44.65  $\pm$  12.02 years, similar to studies conducted by Tripathi *et al.*<sup>[22]</sup> and Jyotiranjan *et al.*<sup>[23]</sup>

In Domain I of drug awareness questionnaire, lowest awareness was observed regarding remembering drug names, possibly due to lower education levels hindering reading and memorization. In Domain III, low awareness was found regarding skipping medication doses and what to do in such cases, likely due to busy lifestyles and inadequate emphasis during clinic visits. The highest awareness was observed in Domains IV and V, indicating the chronic nature of the disease and physician emphasis on their importance. In Domain VI, few patients were aware of antidepressant side effects, possibly due to limited time spent per patient by physicians. However, patients recognized the need to report side effects and seek separate treatment, based on past experiences. The lowest awareness was found in Domain VII, as patients tend to expect quick relief despite being informed about the time required for antidepressants to take effect.

Key takeaways from these results can inform future management strategies for major depressive disorder. Addressing gaps in patient awareness and education, such as treatment response onset, current prescription information, and understanding of side effects, is crucial. Targeted interventions can be developed to provide clear and accessible resources that explain treatment timelines, provide information on medications and their side effects, and emphasize open communication between patients and physicians. Strengthening the patientphysician relationship through improved understanding and active patient participation can enhance treatment adherence and effectiveness, leading to more personalized management strategies.

No significant difference in awareness scores was found between males and females, despite the higher prevalence of MDD in females. Longer disease duration correlated moderately positively with drug awareness scores, indicating improved awareness over time. Lower-middle class patients exhibited the highest drug treatment awareness, followed by upper-middle class patients, possibly due to increased vigilance among the former. Patient socioeconomic status showed a weak negative correlation with drug awareness.

The average number of drugs per encounter in our study was 2.73  $\pm$  1.23, similar to studies by Ghosh and Roychaudhury.<sup>[24]</sup> and Islam *et al.*<sup>[25]</sup> The average number of antidepressants per encounter in our study was 1.36  $\pm$  0.58, consistent with the study by Ghosh and Roychaudhury.<sup>[24]</sup> Compared to Ghosh *et al.*, a low percentage of antidepressants were prescribed by generic name in our study, while in a study by Dutta *et al.* in Uttarakhand, drugs were not prescribed by generic name at all.<sup>[26]</sup> This suggests variations in the practice of prescribing drugs by generic names across different hospital settings.

The majority of drugs prescribed in our study were from the National and WHO essential drug lists,<sup>[27,28]</sup> whereas Ghosh et al. (44.99%) and Dutta et al. (55.39%) had lower utilization of drugs from the national essential list, and Islam et al. (37.5%) had lower utilization from the WHO essential list. These differences could be attributed to variations in health-care priorities based on geographical location, country, availability of medicines, patient preferences, tolerability, and treatment failure. In our study, most prescriptions included one antidepressant, similar to the study by Jyotiranjan et al.[23] Escitalopram was the most commonly prescribed antidepressant, consistent with studies by Tripathi et al., Grover et al., Mishra et al., and Sen et al.[22,29-31] Escitalopram is cost-effective and recommended as a first-line treatment for MDD in the Indian Clinical Guidelines.[32]

Only six FDCs containing antidepressants were prescribed. A combination of escitalopram + clonazepam is approved by the DGCI.<sup>[33]</sup> Except for escitalopram + olanzapine, which may cause tardive akathisia and be prescribed to only two patients with psychotropic depression, the other FDCs are rational.<sup>[34]</sup>

Amitriptyline and Imipramine, although available in hospital formulary, were underutilized due to preference for safer SSRIs like Escitalopram. Amitriptyline and Imipramine were prescribed to a few patients experiencing somatic symptoms like somnolence, headache, and fatigue [Table 5]. Depression is often accompanied by common physical comorbidities such as hypertension and diabetes. A meta-analysis has shown that depression increases the incidence of hypertension.<sup>[35]</sup> Depressive mood is associated with elevated blood pressure levels,<sup>[36]</sup> and diabetes increases the risk of depression, with both conditions exacerbating each other.<sup>[37]</sup> Depression can impair glucose metabolism regulation, leading to an increased mortality risk in diabetic patients.<sup>[38]</sup>

Common ADRs included weakness, fatigue, weight gain, dry mouth, headache, dizziness, constipation, and nausea. Weight gain and somnolence were reported frequently in a study by Al Zaabi *et al.*, where escitalopram was associated with ADRs.<sup>[39]</sup> Weight gain and appetite loss were the most common in a study by Abegaz *et al.* in Ethiopia.<sup>[40]</sup> Escitalopram was found to cause the most ADRs, consistent with a study by Sankhi *et al.* in Nepal, where SSRIs were linked to the majority of ADRs.<sup>[41]</sup>

Causality assessment based on the WHO UMC criteria indicated that most ADRs were possibly related to the antidepressant medication, supported by a study by Munoli and Patil.<sup>[42]</sup> Severity assessment using the modified Hartwig-Siegel Scale revealed that all ADRs were mild in severity, in line with a study by Munoli and Patil, where the majority of ADRs were also mild.<sup>[42]</sup> Considering that most ADRs were mild, it is important to evaluate the risk–benefit ratio before discontinuing treatment or switching to another medication.

According to the modified Schumock and Thornton Scale, all ADRs were deemed nonpreventable, which is consistent with a study by Keche *et al.*,<sup>[43]</sup> where the majority of ADRs were also nonpreventable. This contrasts with the findings of Sankhi *et al.* in Nepal, where most ADRs were classified as "probably preventable."<sup>[41]</sup> The predominance of mild and nonpreventable ADRs suggests satisfactory prescribing practices in the current setting.

The Medication Adherence Rating Scale indicated that most patients had optimal adherence, while a few had poor adherence. However, self-report questionnaires may overestimate adherence behavior, suggesting that actual optimal adherence rates may be lower. This aligns with our study's findings on overall drug treatment awareness in patients. In contrast, a study in France revealed suboptimal adherence in the majority of patients.<sup>[9]</sup> Future studies evaluating medication treatment responses should consider incorporating adherence measures to account for behavioral factors that may influence outcomes. Interventions to improve medication adherence are particularly necessary for more severe cases of MDD.

### CONCLUSIONS

Maximum patients gave correct responses in domains related to follow-up, while minimum patients who gave correct responses were seen in the treatment response awareness domain. The most common antidepressant prescribed was escitalopram, followed by amitriptyline and imipramine. The majority of ADRs were possibly related to antidepressants and were of mild severity and nonpreventable.

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### **Conflicts of interest**

There are no conflicts of interest.

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