

**To Evaluate the Efficacy and Safety Profile of Antidepressant Drugs used in Cases of Depression: A Prospective Cohort Study**Zainishifa M. Mansuri<sup>1</sup>, Rahul Bhavasar<sup>2</sup>, Prashant Parmar<sup>3</sup>, Rahul R. Damor<sup>4</sup>, Hitarthi M. Joshi<sup>5</sup><sup>1</sup>Third year resident, Department of Pharmacology, Parul Institute of Medical Science and Research, Parul University, At & P/O Limda, Waghodia, Vadodara, Gujarat, India<sup>2</sup>Professor & Head, Department of Pharmacology, Parul Institute of Medical Science and Research, Parul University, At & P/O Limda, Waghodia, Vadodara, Gujarat, India<sup>3</sup>Associate Professor, Department of Pharmacology, Parul Institute of Medical Science and Research, Parul University, At & P/O Limda, Waghodia, Vadodara, Gujarat, India<sup>4</sup>Associate Professor, Department of Pharmacology, Dr. N. D. Desai Faculty of Medical Science and Research, Dharmsinh Desai University, Nadiad, Gujarat, India<sup>5</sup>Third year resident, Department of Pharmacology, Parul Institute of Medical Science and Research, Parul University, At & P/O Limda, Waghodia, Vadodara, Gujarat, India

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**Abstract:****Introduction:** Depression, a worldwide health issue, imposes significant disability and socioeconomic consequences on individuals. India is grappling with the consequences of depression among a large portion of its population. Impacts vary from persistent pain to heart-related issues, affecting people of all ages. Depression affects over 280 million people worldwide and is a major contributor to disability, highlighting the need for successful treatment approaches. Although antidepressants are used frequently for the treatment of this disorder, there has been recent controversy about the efficacy and safety of these medications in this population.**Materials and Methodology:** In present study, 50 participants meeting inclusion criteria were observed over a period of two months at Parul Sevashram Hospital, Vadodara. Consent was obtained after being informed, and information regarding the patient such as demographics and treatment details were gathered. An analysis was conducted on the prescription patterns, effectiveness, and side effect of anti-depressants.**Result:** Prevalence of depression among males and females in the 18-80 years of age group was same. Escitalopram was the main SSRI, demonstrating excellent effectiveness and safety. Amitriptyline was popular in the category of TCAs, while venlafaxine and duloxetine were prominent choices in the SNRIs category. Clonazepam was commonly prescribed along with antidepressants.**Conclusion:** This research highlights the equal distribution of depression among genders and how common it is in young adults. Escitalopram was identified as the favoured SSRI, showing effectiveness and safety. Amitriptyline, venlafaxine, and duloxetine stood out as noteworthy within the category of TCAs and SNRIs. Clonazepam was the most commonly prescribed benzodiazepine along with other medications. These results highlight the significance of individualized treatment for depression, considering the effectiveness and safety of medications.**Keywords:** Depression, SSRI, TCA, Hamilton depression rating scale.This is an Open Access article that uses a funding model which does not charge readers or their institutions for access and distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>) and the Budapest Open Access Initiative (<http://www.budapestopenaccessinitiative.org/read>), which permit unrestricted use, distribution, and reproduction in any medium, provided original work is properly credited.**Introduction**

Depression is emerging as a major health issue on a global scale due to its high lifetime prevalence, substantial disability, pain, dysfunction, and economic impact it brings. India is one of the countries with a large population of individuals experiencing depression [1]. Furthermore, major depression is linked to a range of medical issues from chronic pain to coronary artery disease [2]. Depression can impact individuals of all ages and backgrounds throughout their entire lives, from

early childhood to old age [3]. The World Health Organization (WHO) considers depression the main cause of global disability, affecting over 280 million people worldwide [4]. Depressive episodes are identified by feelings of loneliness or sadness, negative thoughts, loss of interest in regular activities, mental sluggishness and difficulty in focusing, trouble sleeping or excessive sleeping, notable changes in weight due to eating habits, restlessness or slowed movements, feelings of guilt

or low self-worth, decreased energy or sex drive that lasts for at least 2 weeks [5]. Antidepressants (AD) are prescribed for treating both depressive and anxiety disorders. Moreover, antidepressants are utilized for treating eating disorders, impulse control disorders, enuresis, sexual dysfunction, and aggression [2].

In major depressive disorders, the efficacy of various antidepressants is similar, with only slight variations, meaning that other factors play a role in determining which drug is chosen [1]. The choice of an appropriate antidepressant for an individual is determined by various factors such as the patient's demographics, illness characteristics, and severity of depression, medication side effects, any other existing medical conditions, and the cost-effectiveness of the treatment [1].

In recent years, there has been a shift in the worldwide prescription trends for antidepressants, moving away from traditional medications such as tricyclics and MAO inhibitors towards selective serotonin reuptake inhibitors (SSRIs) and new types of antidepressants [6]. The main goal of drug utilization research is to promote the rational use of medications, which is difficult to achieve without understanding prescription patterns. Analyzing prescribing patterns involves assessing and recommending changes, if necessary, to the way medical professionals prescribe medications in order to ensure rational and efficient medical care [2].

The objective of this study is to analyze trends in prescription pattern of antidepressants, to evaluate how effective and tolerable antidepressant drugs and to monitor the outcomes of patient.

### Materials and Methodology

The study was a prospective observational, single-center conducted at Psychiatry department of Parul Sevashram Hospital, Parul University, Vadodara,

Gujarat, India, for a period of 2 months after obtaining approval from the Institutional Ethical Committee (October 2023 to November 2023). In the current study, a total of 50 patients were assessed by determining the sample size, adhering to specific inclusion and exclusion criteria. The eligibility criteria for this research include individuals between the ages of 18 to 80 years, of any gender, who had diagnosed as a case of depression. Certain individuals are not eligible to participate, including those who refuse to give consent, individuals with neurological or mental conditions, pregnant women, those experiencing negative reactions to medication, individuals with a history of alcohol or substance abuse, and patients with inadequate data.

Information of the patients meeting the inclusion criteria were documented. The appropriate form was created to gather required and pertinent details. Prior to gathering data, patients were required to give informed written consent and given a patient information sheet to comprehend the study procedure. The investigator did not interfere with the patients' treatment during the observational cohort study. The case record form included patient details like initials, registration number, age, sex, ward/unit of admission, and diagnosis. It also documented treatment specifics like drug name, dose, route of administration, frequency, duration, and any observed adverse drug reactions. Hamilton Depression Rating Scale were recorded for the severity of depression [7]. Data was recorded into a Microsoft Excel spreadsheet and analyzed in percentage format.

### Result

Over the course of two months, 50 prescriptions containing at least one antidepressant were gathered and analyzed, with patients being followed up at 15 and 30 days later.

**Table 1: Age wise distribution of study participant**

Age Group (years)	Number (n) (%)
18 – 30	20 (40 %)
31 – 40	9 (18 %)
41 – 50	9 (18 %)
51 – 60	7 (14 %)
61 - 75	5 (10 %)

Data were presented as n (%).

Table 1 shows how study participants are divided based on their age categories. The majority of patients, total of 20 individuals, were between the ages of 18 to 30, making up 40% of the total participants. In contrast, the smallest number of patients, which was 5 individuals, were aged between 61 to 75, representing 10% of the overall group.

**Table 2: Gender wise distribution of Moderate to Severe Depression.**

Gender	Diagnosis		Total
	Moderate case of depression(n)	Severe Case of depression(n)	
Female	24(48%)	1(2%)	25 (50%)
Male	22(44%)	3(6%)	25 (50%)
Total	46(92%)	4(8%)	50 (100%)

Data were presented as n (%).

Within the female group, 24 participants (48%) had been identified as having moderate depression, while only 1 participant (2%) had been diagnosed with severe depression, making a total of 25 individuals. On the other hand, 22 males (44%) show moderate depression, while 3 males (6%) were identified with severe depression, total of 25 males. The total results show that 46 individuals (92%) had been identified with moderate depression, while 4 individuals (8%) had been diagnosed with severe depression, making up the total number of 50 participants in the study (Table 2).

Table 3 displays the antidepressant drugs and additional medications taken by patients with a diagnosis of depression. Antidepressant medications are categorized as selective serotonin

reuptake inhibitors (SSRI), tricyclic antidepressants (TCA), and serotonin-norepinephrine reuptake inhibitors (SNRI). Out of these, the most commonly prescribed antidepressant is SSRI, given to 45 patients (90%), followed by TCA, which is given to 3 patients (6%), and SNRI, and prescribed for 2 patients (4%).

In terms of other medications taken along with, Clonazepam was the most common, given to 43 patients (86%), followed by Lorazepam and Vitamin B Complex, both taken by 2 patients (4%), and Etizolam, and received by 1 patient (2%) (Fig.1). this research provides understanding of the treatment options used to manage depression, emphasizing the common utilization of SSRI and Clonazepam among the participants.

**Table 3: Antidepressant drugs and concomitant drugs received by patients of depression.**

Drug Classification		Number of patients (%)	Drug	Number of patients (%)
Anti-depressant	SSRI	45 (90%)	Escitalopram	24(48%)
			Sertraline	15(30%)
			Fluoxetine	4(8%)
			Paroxetine	2(4%)
	TCA	3 (6%)	Amitriptyline	3(6%)
	SNRI	2 (4%)	Venlafaxine	1(2%)
Concomitant Drugs	Clonazepam	43 (86%)	Duloxetine	1(2%)
			Lorazepam	2 (4%)
			Etizolam	1 (2%)
			Vit. B Complex	2 (4%)

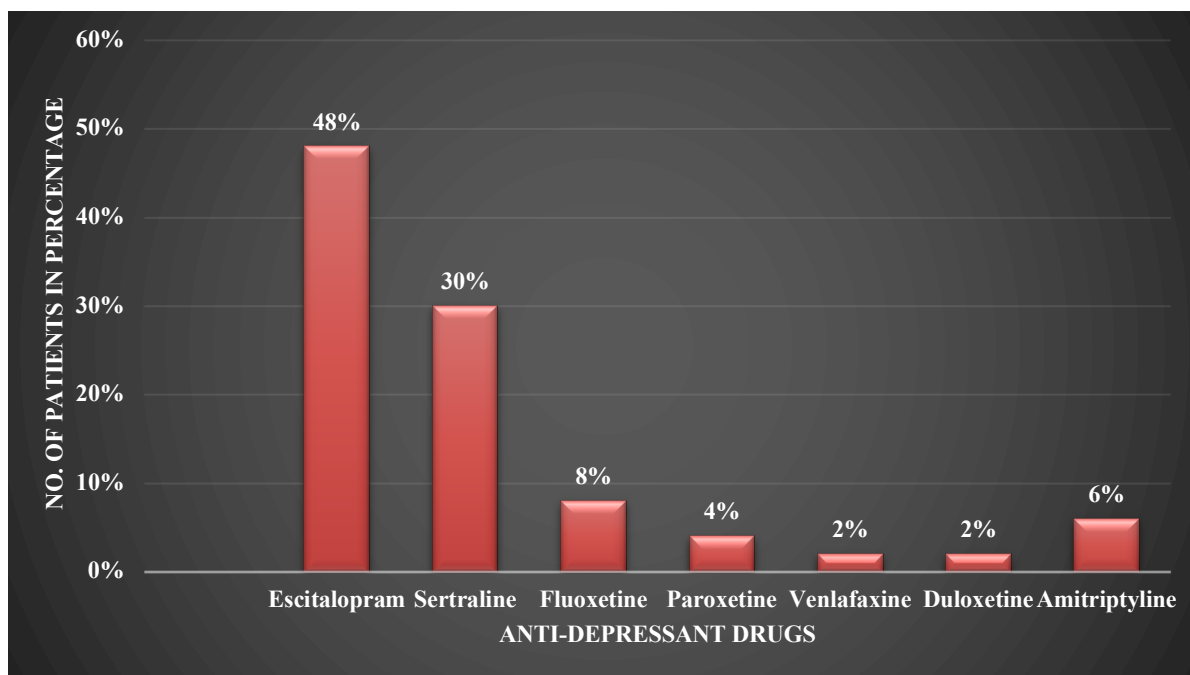


Figure 1: Frequency of anti-depressant drug prescriptions among the patients

Table 4: Comparison of Hamilton depression rating scale score from baseline to day 15 and day 30 in patients of depression [7]

Depression	Baseline	Day 15	Day 30	P value
Moderate	15.10 ± 0.82	13.97 ± 0.71	12.82 ± 0.67	<0.0001
Severe	20.50 ± 0.57	19.25 ± 0.50	17.75 ± 0.50	0.001

Data were presented as Mean ± SD. P<0.05 considered statistically significant by using ANOVA test.

Table 4 gives a comparison of Hamilton depression rating scale scores in patients with depression from the beginning today 15 and day 30[7].

Initially, patients with moderate depression had an average score of 15.10 ± 0.82, which was dropped to 13.97 ± 0.71 by day 15 and then to 12.82 ± 0.67 by the day 30. Statistical analysis indicated a notable drop in scores as time progressed (P < 0.0001). In the same vein, individuals suffering from serious depression showed an initial average score of 20.50 ± 0.57, which fell to 19.25 ± 0.50 on the 15th day and to 17.75 ± 0.50 on the 30th day. Statistical analysis showed a significant decrease in Hamilton depression rating scale scores during the observation period (P = 0.001). These results highlight the effectiveness of the treatment used in improving depressive symptoms, shown by the decrease in Hamilton depression rating scale scores

throughout the study. Table 5 outlines the medication combinations given to patients with a diagnosis of depression. Different combinations were recorded, with the most common one being Escitalopram combined with Clonazepam, given to 22 patients (44%). After that, 11 patients (22%) were prescribed Sertraline in combination with Clonazepam, while 3 patients (6%) received Fluoxetine with Clonazepam and Amitriptyline with Clonazepam each. Individual cases where Duloxetine, Paroxetine, and Venlafaxine were paired with Clonazepam were noted, with each combination representing 2% of all patients. Moreover, different combinations of Lorazepam, Vitamin B Complex, and Etizolam were given to various degrees, adding to the overall treatment plan for managing depression.

These results emphasize the wide range of drug combinations used in clinical settings to treat depression, demonstrating the personalized approach to patient care.

Table 5: Drug combination prescribed to depression patients

Drug combination	No. of patients
Escitalopram + Clonazepam	22 (44%)
Sertraline + Clonazepam	11 (22%)
Fluoxetine + Clonazepam	3 (6%)
Amitriptyline + Clonazepam	3 (6%)
Duloxetine + Clonazepam	1 (2%)

Paroxetine + Clonazepam	1 (2%)
Venlafaxine + Clonazepam	1 (2%)
Escitalopram + Lorazepam	1 (2%)
Sertraline + Vit B Complex	1 (2%)
Escitalopram + Lorazepam + Vit B Complex	1 (2%)
Paroxetine + Clonazepam + Etizolam	1 (2%)

## Discussion

Depression is an important global public health problem and is a major cause of disability and early death [8]. Like present study and other drug utilization, efficacy and safety of different drug groups studies are pointers to prescribing behaviour of clinicians and help in improving it. A prescription therefore may be taken as a reflection of the physician's attitude, whether a private practitioner or working in a tertiary care hospital, towards the disease and the role of the drug in its treatment providing an insight into the nature of the health care delivery system. This research found that the occurrence of depression disorder was the equal in men 25 (50%) and women 25(50%). Studies conducted by Gosh et al. and Hussain et al. both indicated a higher prevalence in one gender compared to the other. In Gosh's study, males had a higher prevalence at 54.67% while in Hussain's study, females had a higher prevalence at 53.75% [2]. A similar type of studies done by Mohammed et al, showed that prevalence was more in males 36 (51.8%) than females 8 (48.2%) [9].

Literature also mentions that females suffer from depression more than males [10]. Biological, life cycle, hormonal and psychosocial factors (poverty and deprivation specifically in India) that women experience may be linked to women's higher depression rate [11]. However, a study was done by Grover et al. has shown equal sex distribution [11]. This research found that the highest rate of depression was observed in individuals aged 18-30 years (40%), and then in the 31-40 age group (18%), a similar study done by Gosh et al. reported a higher prevalence in those aged 18-30 years (43.18%) and 31-40 years (25%) [6]. In our study, 24 patients (48%) were prescribed escitalopram, making it the most commonly prescribed antidepressant, followed by sertraline in 15 patients (30%). Our study's discovery aligns with Tripathi A et al., who also found that escitalopram was the most frequently prescribed antidepressant, with sertraline following closely behind [1].

In a study done by Mishra et al., escitalopram (23.12%) was the most common drug prescribed as monotherapy similar to our study followed by fluoxetine (20.62%), sertraline (11.87%) [12]. Sometimes, patients with depression who start taking antidepressants may also be prescribed a benzodiazepine to help with anxiety and insomnia that often accompany depression, leading to a faster

reduction in depression symptoms. In our research, a combination of Benzodiazepines was prescribed to 46(92%) patients. Clonazepam was the most commonly prescribed benzodiazepine among 43 (86%) patients. The most frequent drug combination used in 22 patients (44%) was escitalopram and clonazepam, similar to the study done by Bushnell et al., where benzodiazepines and antidepressants were also commonly used concomitantly in patients with depression [13].

In the TCAs group, 2 out of 3 patients (66%) experienced minor side effects like dry mouth, constipation, drowsiness, and mild abdominal pain, while in the SSRIs group, 2 out of 44 patients (4.55%) had gastritis, dizziness, and burning sensation. SSRIs do not result in any serious harmful effects that could be fatal. Furthermore, they can be given once a day and involve less need for dose adjustment compared to TCAs. They are more secure and have less side effects in comparison to other antidepressant medications. A study done by Lucca JM et al. described that majority of adverse drug reactions were found from SSRI & SNRI group which is contrary to our study [14].

After the second assessment using the Hamilton depression rating scale, we determined that there was a significant statistical improvement in symptoms following the administration of antidepressant therapy ( $p < 0.05$ ). Our result is in concordance with the study done by Mishra S et al., [12] which shown that all the 13 patients on TCAs had reduced HDRS scores, and in the newer antidepressant group containing 27 patients on SNRIs or NDRI, all 27 of them had reduced HDRS scores on second visit.

## Conclusion

This research highlights the equal distribution of depressive disorder between genders, with the highest occurrence seen in individuals aged 18-30 years. Escitalopram was found to be the primary SSRI, showing the best effectiveness and safety based on Hamilton depression rating scale results and adverse effect observations. Amitriptyline was a common choice of prescription within the category of TCAs, whereas venlafaxine and duloxetine stood out within the SNRIs group. Clonazepam was the most frequently prescribed benzodiazepine along with antidepressant medications. Escitalopram + Clonazepam was the most frequent used combination.

All the three major anti-depressant groups are decreasing the HDRS scoring. These results provide insights into the pharmacological treatment of depression, highlighting the importance of personalized approaches based on drug effectiveness and safety factors.

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