

# A Comparative Study on Safety Profile and Efficacy of Vilazodone and Escitalopram across Symptoms and Severity of Depression Disorder

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**ABSTRACT:** Depression is different from usual mood fluctuations and short-lived emotional responses to challenges in everyday life. The aim of the study is to assess the safety profile and relative efficacy of Vilazodone and Escitalopram in depression patients. The prospective observational comparative study conducted for a period of 6 months. The data was collected from 90 enrolled subjects with the help of questionnaire and scales. Statistical results for Vilazodone showed P-value for HAM-D & BMI was  $**P<0.01$  was highly significant BDI  $*P<0.003$  & ASEX  $*P<0.002$  were significant and for escitalopram P-value for HAM-D  $**P<0.01$  was highly significant BDI  $*P<0.002$  & BMI  $*P<0.003$  were significant and the ASEX  $*P<0.003$  was significant. Escitalopram has high efficacy when compared with Vilazodone and it possess with ADRs like sexual dysfunction and obesity, whereas for Vilazodone it has low efficacy when compared with escitalopram and doesn't showed any ADRs like sexual dysfunction and obesity.

**KEYWORDS:** Antidepressant (AD), Diagnostic and Statistical Manual of Mental Disorders (DSM), Major Depressive Disorder (MDD), Seasonal Affective Disorder (SAD), Vilazodone, Escitalopram.

## I. INTRODUCTION:

The term depression also began to appear in the 19th century, to indicate a state of sadness. Depression is a widespread, devastating illness, resulting in enormous personal suffering and economic loss. Moreover, currently available treatments have significant limitations (i.e., low response rates, treatment resistance, high incidence of relapse, and a time-lag of weeks to months for a response), highlighting a major unmet need for more

efficacious and faster-acting antidepressants, particularly with the high suicide rates in depression.

Depression is a common illness worldwide, with more than 300 million people affected. Depression is different from usual mood fluctuations and short-lived emotional responses to challenges in everyday life. At its worst, depression can lead to suicide. Close to 800 000 people die due to suicide every year. Suicide is the second leading cause of death in 15-29-year-olds.

## TYPES OF DEPRESSION:

Two of the most common forms of depression are:

- Major depression—having symptoms of depression most of the day, nearly every day for at least 2 weeks that interfere with your ability to work, sleep, study, eat, and enjoy life. An episode can occur only once in a person's lifetime, but more often, a person has several episodes.

- Persistent depressive disorder (dysthymia)—having symptoms of depression that last for at least 2 years. A person diagnosed with this form of depression may have episodes of major depression along with periods of less severe symptoms.

Some forms of depression are slightly different or they may develop under unique circumstances, such as

- ✓ Perinatal Depression: Women with perinatal depression experience full-blown major depression during pregnancy or after delivery (postpartum depression).

- ✓ Seasonal Affective Disorder (SAD): SAD is a type of depression that comes and goes with the seasons, typically starting in the late fall and early winter and going away during the spring and summer.

Psychotic Depression: This type of depression occurs when a person has severe depression plus

some form of psychosis, such as having disturbing false fixed beliefs (delusions) or hearing or seeing upsetting things that others cannot hear or see (hallucinations).

## II AIMS AND OBJECTIVES:

### AIMS

The aim of the study is to assess the safety profile and relative efficacy of Vilazodone and Escitalopram in depression patients.

### OBJECTIVES

#### A) Primary objective

To assess the safety profile and relative efficacy of Vilazodone and Escitalopram in depression patients.

#### B) Secondary objective

To analyse the age, gender and socio demographic data.

To analyse the complication of getting co morbidities like obesity and sexual dysfunction.

## III METHODOLOGY

**Type of Study:** Prospective Observational Study

**Place of Study:** Dr.Hari S Neuro Mind Clinic

**Study Period:** June 2019 to December 2019

**Study Population:** 90

**Sampling Technique:** Random Sampling

## IV METHODS

After obtaining the approval from institutional ethical committee, data of patients matching inclusion criteria were recorded after getting informed consent. Data required for conducting the study (demographic details, chief complaints, lab data, and ongoing treatment) were recorded in previously prepared case report form.

### Inclusion criteria

- The patients who are diagnosed with depression as per ICD - 10 criteria.
- Patients with 18 - 68 years age.
- Patients of either sex.
- Patients prescribed with either Vilazodone or Escitalopram.
- Patients who are willing to give voluntary informed consent.

### Exclusion criteria

- Patients who are not willing to participate in the study.
- Specialized population like paediatrics, pregnant women, breast feeding women.
- Patients from other surgical departments and ambulatory visit.

- Prescription with other antipsychotics.
- Patients who are having depression with other organ pathological conditions.

### Statistical Analysis

Statistical analysis will be performed by using SPSS and results will be analysed and representing in the form of table and bar diagram.

### Study Procedure:

- This is the prospective observational study will be conducted for the period of 6 month.
- After obtaining ethical clearance the study will be conducted in outpatient psychiatric department.
- The patients of Depression were diagnosed by a psychiatrist according to International Classification of Diseases-10 (ICD-10) criteria by World Health Organization.
- Patient will be identified on the basis of inclusion and exclusion criteria.
- The informed consent will be obtained from the patient representative.
- The study will be conducted in 90 -100 patients of depression, prescribed with Vilazodone and Escitalopram.
- Extraction of required data from case record, direct interview to the patient and patient representative.
- Data will be recorded in specially designed data collection form for the study. The patient demographic details, diagnosis, prescribed drugs with dose, frequency and administration of medications will also be recorded in data collection form.

Section A- Demographic details of the subjects involved in the study.

Section B- Diagnosis

Section C- Medication data such as class, dose, frequency, route of administration.

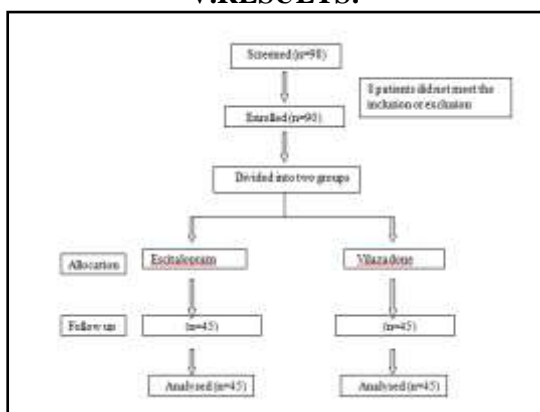
Section D- Questionnaire to assess the efficacy and safety of drug among the out patients.

- Comparing efficacy of Vilazodone and escitalopram by examine symptoms and severity according to BECKS (BIC), HAM-D and ASEX scales.
- The obtained information will be analysed and representing in the form of table and diagrams in SPASS.
- Summarizing and preparation of summary data by appropriate statistical methods.
- Submission of report.

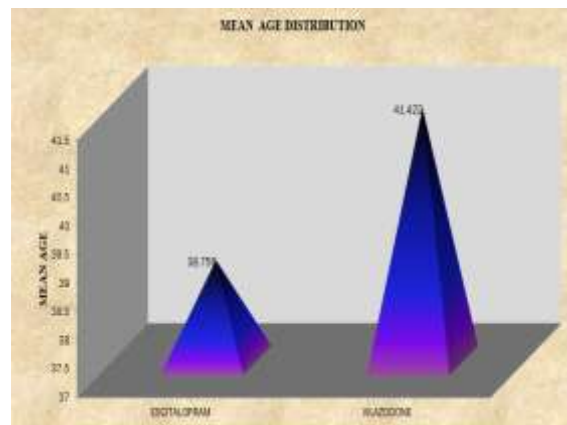
**Ethical Clearance**

Institutional review board has accepted the project.

**V.RESULTS:**



**Figure: Pictorial representation of the Study**



**Figure.1**

In the present investigation, it was observed that the Mean age group for the patients who administered with drug Escitalopram was found to be 38.7% and the patients who administered drug Vilazodone was 41.22%.

**A.AGE GROUP DISTRIBUTION:**

AGE GROUP	ESCITALOPRAM		VILAZODONE		TOTAL
	COUNT	%	COUNT	%	
18-28	11	24.4%	12	26.7%	25.6%
29-38	14	31.1%	19	20%	25.6%
39-48	11	24.4%	8	17.8%	21.1%
49-58	3	6.7%	7	15.6%	11.1%
59-68	6	13.3%	9	20%	16.7%

**Table.1**

From the data obtained with the above study containing group of 90 Patients, it was observed that the age group for the patients who administered with drug Escitalopram and Vilazodone was found to be 25.6% in the age group of 18-28 & 29-38.

**B.MEAN AGE DISTRIBUTION**

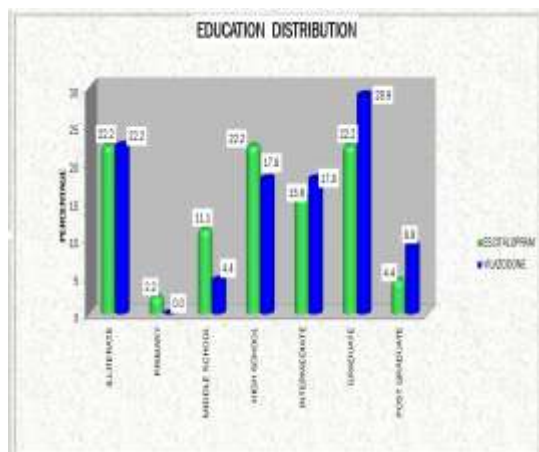
**C.GENDER DISTRIBUTION**

SEX	ESCITALOPRAM		VILAZODONE		TOTAL
	Count	%	Count	%	
MALES	19	42.2%	25	55.6%	48.9%
FEMALES	26	57.8%	20	44.4%	51.1%

**Table.2**

Gender distribution of the total 90 patients was calculated from the above graph and was found that 48.9% of males & 51.1 % of females were prescribed with both drugs.

**D. EDUCATIONAL DISTRIBUTION**



**Figure.2**

The above data was analysed for Educational distributional information based on the literacy and was found that, among the total 90 patients maximum percentage of people who received both the drugs were Graduates with 25.6% and the lowest was in Primary students with 1.1%.

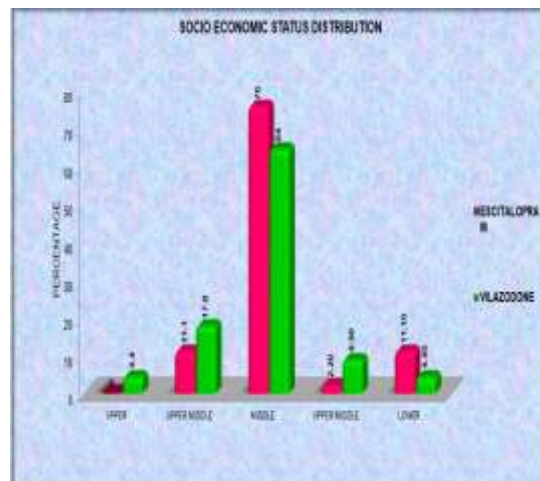
**E. OCCUPATIONAL DISTRIBUTION**

OCCUPATION DISTRIBUTION	ESCITALOPRAM		VILAZODONE		TOTAL
	COUNT	%	COUNT	%	
PROFESSION	6	13.3%	7	15.6%	14.4%
SEMI PROFESSION	3	6.7%	3	6.7%	6.7%
FARMER/BUSINESS	6	13.3%	8	17.8%	15.6%
SKILLED WORKER	2	4.4%	3	6.7%	5.6%
SEMI SKILLED WORKER	0	0%	1	2.2%	1.1%
UNSKILLED WORKER	2	4.4%	0	0%	2.2%
UN EMPLOYED	26	57.8%	23	51.1%	54.4%

**Table.3**

From The above data of a total of 90 patients it was observed that Unemployed patients with 54.4% was found to be high and semi-skilled persons with 1.1% was found to be low, who are receiving both the drugs.

**F. SOCIO-ECONOMIC STATUS:**



**Figure.3**

From The above data of a total of 90 patients it was observed that middle class patients with 70.0% was found to be high and upper with 2.2% was found to be low, who are receiving both the drugs.

**G. MARITAL STATUS:**

MARITAL STATUS DISTRIBUTION	ESCITALOPRAM		VILAZODONE		TOTAL
	COUNT	%	COUNT	%	
Un married	9	20%	7	15.6%	17.8%
Married	36	80%	29	64.4%	72.2%
Separated	0	0%	6	13.3%	6.7%
Divorced	0	0%	3	6.7%	3.3%

**Table.4**

above data was analyzed for marital status distribution information and found that, among the total 90 patients maximum percentage of people who received both the drugs were married People with 72.2% and the lowest was divorced with 3.3%.

**H. DETERMINATION OF P VALUE BY USING T-TEST IN ESCITALOPRAM GROUP FOR ESCITALOPRAM:**

The below data was analysed by using SPASS software and the mean of the HAM-D, BDI, ASEX, BMI for the Initial month (ZERO) and the final (SIXTH) month was determined. Both the Initial and Final months mean values were assessed and the P-Value of the above two means were determined.

From the Obtained results of t-test for the Initial and final months mean, It was observed that the obtained p-value for HAM-D **\*\*P<0.001** was highly significant, BDI **\*P<0.002**, & BMI **\*P<0.003** were significant and the ASEX **\*P<0.721** was Insignificant.

**Note:** **\*\*P<0.01** INDICATES highly significant, **\*P<0.05** Indicates significant

ESCITALOPRAM					
		N	Mean	Std. Deviation	P-VALUE
Pair 1	HAM -D ZERO MONTH	45	17.067	4.4436	0.001
	HAM -D SIXTH MONTH	45	7.822	1.7618	
Pair 2	BDI ZERO MONTH	45	24.133	5.6472	0.002
	BDI SIXTH MONTH	45	10.333	4.5025	
Pair 3	ASEX ZERO MONTH	45	13.689	2.1194	0.721
	ASEX SIXTH MONTH	45	13.556	2.5722	
Pair 4	BMI ZERO MONTH	45	24.449	3.2109	0.003
	BMI SIXTH MONTH	45	25.518	3.5534	

**Table.5 ESCITALOPRAM**

**I.DETERMINATION OF P VALUE BY USING T-TEST IN VILAZODONE GROUP1:**

VILAZODONE					
		N	Mean	Std. Deviation	P-VALUE
Pair 1	HAM -D ZERO MONTH	45	15.311	2.9835	0.001
	HAM -D SIXTH MONTH	45	8.133	1.9141	
Pair 2	BDI ZERO MONTH	45	19.267	4.1363	0.003
	BDI SIXTH MONTH	45	9.111	2.2485	
Pair 3	ASEX ZERO MONTH	45	13.622	1.4661	0.021
	ASEX SIXTH MONTH	45	14.089	1.8194	
Pair 4	BMI ZERO MONTH	45	25.344	5.7360	0.001
	BMI SIXTH MONTH	45	25.820	5.7348	

**Table.6 VILAZODONE**

**Note:** **\*\*P<0.01** INDICATES highly significant, **\*P<0.05** Indicates significant

**FOR VILAZODONE:**

The above data was analysed by using SPASS software and the mean of the HAM-D, BDI, ASEX, BMI for the Initial month (ZERO) and the final (SIXTH) month was determined. Both the Initial and Final months mean values were assessed and the P-Value of the above two means were determined.

From the Obtained results of t-test for the Initial and final months mean, It was observed that the obtained p-value for HAM-D & BMI was **\*\*P<0.01** was highly significant, BDI **\*P<0.003** & ASEX **\*P<0.021** were significant.

**VI DISCUSSION**

The demographic profile revealed that most patients who administered with drugs Escitalopram and Vilazodone was found to be 25.6% in the age group of 18-28 & 29-38. In our study more no. of females (51.1%) are suffering from depression when compared with males (48.9%) , likewise in our findings literates were more prone for suffering with depression than illiterates(22.2%). According to our firm we have found that unemployed (54.4%) people were suffering additional amount of depression when estimated with the profession (14.4%), semi profession (6.7%), skilled worker (5.6%), semi-skilled worker (1.1%), unskilled worker (2.2%) and farmers (15.6%).

In our study the patients who were married (72.2%) are highly suffering from depression when measured with rest category like unmarried (17.8%), separated (6.7%) and divorced (3.3%).

In this investigation patients who are in middle class groups (70.0%) were more exceedingly suffering from depression when collate with other groups like upper middle, lower middle, and upper lower and lower.

From 0 month to 6 month both Vilazodone and Escitalopram showed a gradual decrease in the mean score of the HAM – D & BDI. This indicates that both drugs are good in treating symptoms of MDD.

Findings of our study showed that Escitalopram has high efficacy when compared with Vilazodone and it possess with ADRs like sexual dysfunction and obesity, whereas for Vilazodone it has low efficacy when compared with Escitalopram and doesn't showed any ADRs like sexual dysfunction and obesity.

## VII CONCLUSION

In the frame work of this study aimed to determine compare the safety and efficacy of Vilazodone and Escitalopram for MDD. Depression is a condition which is widely distributed in all age groups mainly and in our studies the range of females was more when estimated with males.

Escitalopram has high efficacy when compared with Vilazodone and it possess with ADRs like sexual dysfunction and obesity, whereas for Vilazodone it has low efficacy when compared with Escitalopram and doesn't showed any ADRs like sexual dysfunction and obesity.

In the current study the age group of 29–38 years are highly constituent in Escitalopram and for Vilazodone the age group of 18–28 were highly appeared, we have found that unemployed people were suffering additional amount of depression

In this quest the patients who were married and patients who are in middle class groups were more exceedingly suffering from depression.

By considering all the above data the study concludes that Escitalopram should be highly preferred in patients suffering from severe and moderate depression.

### STRENGTHS:

- ✓ This study will helps in reducing the rate of relapse, rate of re-hospitalisation and length of re-admission.
- ✓ Separate room for assessing patients (confidentiality).
- ✓ Data collection was qualitative method (multiple scales and questionnaires used).
- ✓ It consumes less time to analyse data (t-test used).

### LIMITATIONS:

- ✓ Small sample size
- ✓ Time consuming process (multiple scales and questionnaires used)

## VIII ACKNOWLEDGEMENT

It gives us immense pleasure to express our gratitude to everyone who helped us to complete this project, the work on this project has been as interesting, often exciting, sometimes challenging, but always interesting and an enjoyable experience.

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