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Research Article

A COMPARATIVE STUDY OF EFFICACY, SAFETY, AND ONSET OF ACTION OF VILAZODONE WITH ESCITALOPRAM IN PATIENTS OF MAJOR DEPRESSIVE DISORDER AT TERTIARY CARE HOSPITAL

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ABSTRACT

Objective: To compare efficacy, safety, and onset of action of Vilazodone with Escitalopram in treatment of major depressive disorder (MDD).

Methods: A prospective, randomized, active-controlled, and parallel–group comparative open label study was conducted among 92 patients of MDD attending psychiatry OPD of a tertiary care center. They were divided into control and experimental groups receiving Escitalopram and Vilazodone, respectively. Hamilton depression rating scale (HAM-D), Hamilton anxiety rating scale (HAM-A), Montgomery-Asberg depression rating scale (MADRS), clinical global impression improvement (CGI-I), and CGI-severity (CGI-S) scores were assessed at the end of 1st, 2nd, 4th, and 12th weeks in both the groups.

Results: There was significant decrease in HAM-D, HAM-A, MADRS, CGI, and CGI-S scores in control as well as the experimental groups. Experimental group receiving Vilazodone showed significant decrease in the scores as compared to control group ($p<0.001$) at the end of 2nd and 4th week. Although the number of adverse effects were more in the Vilazodone group leading to higher score on UKU scale, the difference was not statistically significant.

Conclusion: The present study showed clinical advantages of use of Vilazodone over Escitalopram with improvement in all the scores. Significant reduction in scores was seen as early as 1 week in Vilazodone group which justifies its early onset of action and superiority over selective serotonin reuptake inhibitors.

Keywords: Efficacy, Vilazodone, Escitalopram, Major depressive disorders.

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INTRODUCTION

Depression is a major disorder of public health importance and is one of the major cause of morbidity as well as mortality, and it is predicted to be second leading cause of burden of disease worldwide by 2030 [1]. According to recent WHO 2017, statistics approximately 300 million people suffer from depression worldwide with females affected twice as compared to males [2]. The prevalence of depression in India is 1.8–39.6% [3]. Major depressive disorder (MDD) is a serious chronic and recurrent psychiatric illness and accounts for 10–14% of all patients seen by the primary care physicians [4-6].

According to the American psychiatry association guidelines the treatment protocol for MDD may include pharmacotherapy, psychotherapy, and somatic therapies such as electroconvulsive therapy (ECT), transmagnetic stimulation, or light therapy. Out of all these modalities, antidepressant medications are most widely used and accepted modality of treatment [7]. About 50 years ago, tricyclic antidepressants and monoamine oxidase inhibitors came into existence.

However, the advent of selective serotonin reuptake inhibitors (SSRI) revolutionized the treatment of depression and till date is the greatest discoveries in the treatment of depression. The introduction of SSRI markedly reduced suicide rates in both adults and adolescents, but they were not entirely free of burdensome side effects such as increased sleep, gastric discomfort in the early stages, and sexual adverse effects to name a few. However, the main drawback of SSRI agent is their delayed onset of action.

An average of 2 weeks delay in the start of the treatment with antidepressant agents and onset of clinical antidepressant action has been seen with almost all SSRI which forms the main setback of their clinical profile. This delay in onset of action of SSRI has been attributed to the time taken for the down regulation of somatodendritic 5HT1Areceptors. With a view of developing a single drug which combines both the actions 5HT1Aagonism and SERT (serotonin transporter) antagonism, the molecule Vilazodone was developed in 2011. Vilazodone is technically not a SSRI as it has greater affinity for 5-HT1Areceptor (0.2 nm) than it does for 5-HT reuptake pump (0.5nm). Mechanism of action of Vilazodone in brief is as follows, in humans 5-HT1A receptors are primarily presynaptic in the raphe nuclei and post synaptic 5-HT1A receptor predominates in the neocortex and limbic regions of brain [8]. Presynaptically, 5-HT1A is auto receptor, that is, serotonin stimulation of these receptors results in inhibition of firing of 5-HT neurons, while, postsynaptically, they may be involved in downstream serotonergic effects such as sexual function [9]. SSRIs are thought to work as antidepressant by increasing 5-HT concentration in the synapse, but their initial effect is to turn off 5-HT neuronal firing as a result of increased concentration of 5-HT at presynaptic 5-HT1A auto receptors.

Subsequently, these 5-HT1A auto receptors subsensetize such that 5-HT neuronal firing rate returns to normal. The time course for this subsensetization parallels the onset of SSRI antidepressant efficacy [10-12]. Vilazodone as a newer antidepressant is approved by US Food and Drug Administration in January 2011 [13] and CDSCO in August 2015 [14]. As Vilazodone shows partial agonism at 5HT1Areceptors that it is classified as Serotonin Partial Agonist Reuptake Inhibitor [15]. Dual action on serotonin reuptake inhibition and partial agonism on 5HT1A increase its antidepressant effect and its

tolerability. Studies have shown that Vilazodone has better side effect profile and early onset of action as compared to other SSRI [13].

Escitalopram is s-enantiomer of Citalopram, which is one of the most frequently used SSRI for the treatment of MDD in individuals more than 12 years of age. It is efficacious cost effective and is associated with highest probability of remission [7]. A meta-analysis suggests superiority of Escitalopram as compared to other SSRI [7,16]. Considering limitations associated with use of Escitalopram for treatment of MDD and few previous studies done comparing Vilazodone with Escitalopram and their conflicting results in terms of efficacy, the present study was planned to compare efficacy, safety, and onset of action of Vilazodone with Escitalopram [1,7,17].

MATERIALS AND METHODS

A prospective, randomized, active-controlled, and parallel–group comparative open-label study was conducted during February1, 2019–July 30, 2020, among 92 patients of MDD diagnosed by a qualified psychiatrist as per the diagnostic and statistical manual of mental disorder, fifth edition (DSM –V) attending psychiatry OPD of a tertiary care center, meeting inclusion criteria.

After permission of the Institutional Ethics Committee with vide letter no. 63/2018, and registration to clinical trial registry India (CTRI) with vide letter no. CTRI/2019/01/017302, the patients were invited to participate in the study. Good Clinical Practice (GCP) guidelines were strictly followed. A written informed consent from the patient or legal guardian of patient was taken after explaining nature and purpose of study in their own language. The patient information sheet containing all the necessary details of study was provided to patient. Eligible patients were randomized using block permutation method with allocation ratio of 1:1 to receive either Escitalopram or Vilazodone. The patient receiving Escitalopram was considered as control (C) group and Vilazodone as experimental (E) group.

Sample size

In the present study to compare, the efficacy of Vilazodone and Escitalopram was determined mainly by HAM –D score from a study by Kudyar *et al.* [7], where Mean HAM-D score in Escitalopram and Vilazodone group were 6.06 and 8.29 with SD of 0.93 and 0.9, respectively. Sample size was calculated using OpenEpi software which was 05 in each group. To know, the difference in efficacy of both drugs second sample was calculated which was 46. Hence, we decided to include highest sample size of 46 in each group.

Inclusion criteria

The following patients were included in the study:

1. Patients of either sex with age between 18 and 65 years.
2. Newly diagnosed MDD patients meeting DSM 5 criteria for depression
3. Patient who give written informed consent.

Exclusion criteria

The following patients were excluded in the study:

1. Pregnant or nursing women.
2. Patients with high risk of suicidal tendency or previous suicide attempt within 6 months.
3. Patients with bipolar disorder, drug abuse or dependency, post-traumatic stress disorder, obsessive – compulsive disorder.
4. Patients with previous depression resistant to antidepressants and those who had taken treatment with ECT in previous 3 months or formal psychotherapy within 1 month.
5. Patients on other antidepressants.
6. Patients with neurological disorders (dementia, seizures, and stroke), obesity with functional impairment, serious or unstable organic disorder (neoplasia, cardiovascular, pulmonary, and uncontrolled type 1 or 2 diabetes.)
7. Any other medical disorder which is confounding our inclusion diagnosis.
8. Patients with drug intake for psychosis or anxiety.
9. Any history of allergy to the drugs.

Procedure

Before starting treatment, baseline (day 1) Hamilton depression rating scale (HAM-D), Hamilton anxiety rating scale (HAM-A), Montgomery-Asberg depression rating scale (MADRS), and clinical global impression Severity (CGI-S) score were taken.

Furthermore, baseline (day 1) blood investigations such as complete blood count, liver function test, and kidney function test (KFT) were done after which treatment with either Vilazodone (10 mg) or Escitalopram (10 mg) orally as prescribed by psychiatrist was started. Patients were advised to take Vilazodone with food. Dose of the drug was doubled every week maximum up to 40 mg for Vilazodone and for Escitalopram dose was increased by 5 mg every week maximum up to 20 mg if inadequate response is obtained. Subsequent follow-up was taken at 1st, 2nd, 4th, and 12th week and changes in the HAM-D, HAM-A, MADRS, clinical global impression improvement (CGI-I), and clinical global impression severity (CGI-S) Score were recorded. Follow-up blood investigation was done at 4th and 12th week. The primary efficacy outcomes were taken as change from the baseline in the values of HAM-D17 total score (change from baseline to last post baseline assessment). Secondary outcome measurers were HAM-A, MADRS and CGI-I, and CGI-S score.

HAM-D is also known as HDRS, which is a multiple item questionnaire used to provide an indication of depression and as a guide to evaluate recovery. The original version contained 17 items and designed for adults to rate severity of their depression based on mood, feeling of guilt, suicide ideation, insomnia, anxiety, weight loss, and other somatic symptoms. HDRS-21 is a 21-item HAM-D scale which was used in the present study to evaluate the patient's symptoms of depression. Each item on the questionnaire is scored on three or five points scale. Depending on the score depression was evaluated as 0–7 normal score, 8–13 as mild depression, 14–18 as moderate depression, 19–22 as severe depression, and >23 as very severe depression.

HAM-A scale is psychological questionnaire developed to measure patient's symptoms of anxiety which includes 14 parameters such as anxious mood, tension, fears, insomnia, somatic complaint, and behavior at the time of interview. Each item is scored from 0 to 5 based on severity of the symptoms. The total score was calculated for all items.

MADRS is ten item questionnaire used to measure severity of depression. Questionnaire included apparent sadness, reported sadness, inner tension, reduced sleep, reduced appetite, concentration difficulties, lassitude, inability to feel, pessimistic thoughts, and suicidal thoughts. The overall score ranges from 0-60. Rating lied on defined scale steps (0,2,4,6). The usual cutoff points was 0–6 as normal/symptom absent, 7–9 mild depression, 20–34 moderate depression, and >34 – severe depression.

Clinical global impression scale (CGI) comprised two companion, one item measures severity of psychopathology from 1 to 7 and other measures change from the initiation of treatment on similar seven point Scale. CGI-severity (CGI-S) ask the clinician one question "considering your total clinical experience with this, how mentally ill is the patient at this time ?," which is rated on following seven points, scale:1=Normal, not at all ill; 2=Borderline mentally ill; 3=Mildly ill, 4=Moderately ill; 5=Markedly ill; 6=Severely ill; and 7=Among most extremely ill patients.

For CGI-I, CGI-S score obtained at baseline (initiation) visits serves a good basis for making this assessment. Again following one query is rated on seven point scale: compared to patients condition at admission to the project (before medication initiation), this patient condition is 1=Very much improved since the initiation of treatment, 2=Much improved 3=Minimally improved, 4=No change from baseline, and 5=Minimally worse since initiation of treatment. It is a clinician rated scale with well-defined items developed to provide a comprehensive rating of side effects with psychopharmacological medications.

Statistical analysis

Data were feed to Microsoft excel. Analysis was done with statistical software SPSS version 22. Results on continuous measurements were presented on mean±SD (min-max) and results on categorical measurements were presented in number (%). Statistical significance was assessed at 5% level of significance. Inferential statistics was done using independent t-test.

RESULTS

Ninety-two patients were enrolled in the present study after meeting the inclusion and exclusion criteria, of which 90 patients given follow-up to 12 weeks with two patients lost to follow-up (Table 1).

Table 1 shows changes in HAM-D scores at various time intervals, patients who were selected for Vilazodone the mean score on HDRS scale at baseline were found to be have 22.23±4.61, and at 1st, 2nd, 4th, and 12th week scores fell up to 15.3±4.48, 8.51±3.16, 3.15±2.18, and 1/.71±1.39, respectively.

Patients who were selected for Escitalopram found to have baseline score of 22.91±4.26, which on 1st, 2nd, 4th, and 12th week reduced to 17.66±4.38, 11.88±3.40, 4.24±3.17, and 2.02±1.42 respectively.

There was fall in scores on HDRS in both the groups at 1st week and 2nd week fall in scores on which HDRS was significant at 1st week and strongly significant at 2nd week (p≤0.001**). However, the fall in scoring was more in patients who were on Vilazodone, the difference was found to be statistically significant (p<0.001**).

Table 2 shows changes in HAM-A scores at various time intervals. Patients who were selected for Vilazodone have the mean score on HDRS scale at baseline 23.64±4.53, and at 1st, 2nd, 4th, and 12th week scores fell up to 16.50±4.35, 9.81±3.53, 3.02±2.04, and 1.47±1.33, respectively.

Patients who were selected for Escitalopram found to have baseline score of 24.78±4.96 which on 1st, 2nd, 4th, and 12th week reduced to 23.10±22.10, 13.45±4.12, 4.41±3.34, and 2.39±4.51, respectively. There is highly significant change in HAM-A score at 2nd week (p<0.001**).

There was fall in scores on HAM-A in both the groups at 2nd week and 4th; however, the fall in scoring was more in patients who were on Vilazodone, the difference is found to be statistically significant (p<0.001**).

Table 1: HAM-D- A comparison in two groups of patients studied at different study points

HAM-D	Treatment received		Total	p value
	Group C	Group E		
Baseline	22.91±4.26	22.23±4.61	22.57±4.42	0.469
1st week	17.66±4.38	15.3±4.48	16.50±4.56	0.014*
2nd week	11.88±3.40	8.51±3.16	10.20±3.68	<0.001**
4th week	4.24±3.17	3.15±2.18	3.70±2.76	0.061+
12th week	2.02±1.42	1/.71±1.39	1.86±1.40	0.297

HAM-D: Hamilton depression rating scale

Table 2: HAM-A: A comparison in two groups of patients studied at different study points

HAM-A	Treatment received		Total	p value
	Group C	Group E		
Baseline	24.78±4.96	23.64±4.53	24.22±4.76	0.252
1st week	23.10±22.10	16.50±4.35	19.87±16.34	0.055+
2nd week	13.45±4.12	9.81±3.53	11.67±4.24	<0.001**
4th week	4.41±3.34	3.02±2.04	3.73±2.85	0.020*
12th week	2.39±4.51	1.47±1.33	1.94±3.37	0.201

HAM-A: Hamilton anxiety rating scale

Table 3 shows changes in MADRS scores at various time intervals. Patients who were selected for Vilazodone have the mean score on MADRS scale at baseline 24.11±7.81, and at 1st, 2nd, 4th, and 12th week scores fell up to 17.34±6.24, 10.31±3.63, 3.40±2.06, and 1.88±1.52, respectively. In patients who were selected for Escilatopram found to have baseline score of 26.48±6.47 which on 1st, 2nd, 4th, and 12th week scores reduced to 64.93±293.82, 18.06±15.91, 5.50±3.94, and 2.02±1.54, respectively. There is highly reduction in MADRS score at 2nd and 4th week (p=0.002**) in both the groups.

Table 4 shows changes in CGI-S scores at various time intervals. Patients who were selected for Vilazodone have the mean score on CGI-S scale at baseline 4.86±0.50, and at 1st, 2nd, 4th, and 12th week scores fell up to 3.79±0.66, 2.47±1.04, 1.15±0.47, and 1.00±0.00, respectively.

Patients who were selected for Escitalopram found to have baseline score of 5.51±3.38, which on 1st, 2nd, 4th, and 12th week reduced to 4.60±2.52, 3.50±1.78.,54, 1.28±0.58, and 1.00±0.00, respectively. There is significant reduction at the end of 1st week and highly significant reduction in CGI-S score at 2nd week (p=−0.042*).

Table 5 shows changes in CGI-I scores at various time intervals. Patients who were selected for Vilazodone have the mean score on CGI-I scale at the end of 1st week which was 2.93±0.45 at 2nd, 4th, and 12th week scores fell up to 2.34±1.38, 1.15±0.36, and 1.00±0.00, respectively.

Patients who were selected for Escitalopram found to have score at the end of 1st week 3.58±2.80 which at, 2nd, 4th, and 12th week reduced to 2.65±1.81, 1.23±0.43, and 1.00±0.00, respectively. There is significant change in CGI-I score at the end of 2nd and 4th week (p=−0.030*) (Table 6).

Table 3: MADRS: A comparison in two groups of patients studied at different study points

MADRS	Treatment received		Total	p value
	Group C	Group E		
Baseline	26.48±6.47	24.11±7.81	25.32±7.22	0.115
1st week	21.59±5.98	17.34±6.24	19.51±6.44	0.001**
2nd week	18.06±15.91	10.31±3.63	14.27±12.23	0.002**
4th week	5.50±3.94	3.40±2.06	4.47±3.32	0.002**
12th week	2.02±1.54	1.88±1.52	1.95±1.52	0.678

MADRS: Montgomery-Asberg depression rating scale

Table 4: CGI-S: A comparison in two groups of patients studied at different study points

CGI-S	Treatment received		Total	p value
	Group C	Group E		
Baseline	5.51±3.38	4.86±0.50	5.19±2.45	0.209
1st week	4.60±2.52	3.79±0.66	4.21±1.89	0.042*
2nd week	3.50±1.78	2.47±1.04	3.00±1.55	<0.001**
4th week	1.28±0.58	1.15±0.47	1.22±0.53	0.277
12th week	1.00±0.00	1.00±0.00	1.00±0.00	-

CGI-S: Clinical global impression-severity

Table 5: CGI-I-A Comparison in two groups of patients studied at different study points

CGI-I	Treatment Received		Total	p value
	Group C	Group E		
Baseline	-	-	-	-
1st week	3.58±2.80	2.93±0.45	3.26±2.04	0.130
2nd week	2.65±1.81	2.02±0.54	2.34±1.38	0.030*
4th week	1.23±0.43	1.06±0.25	1.15±0.36	0.025*
12th week	1.00±0.00	1.00±0.00	1.00±0.00	-

CGI-I: Clinical global impression improvement

Table 6: UKU scale: A comparison in two groups of patients studied at different study points

Side effects	Treatment received		Total (n=92)	p value
	Group C (n=46)	Group E (n=46)		
Nausea/ vomiting	29 (63.1%)	30 (65.2%)	59 (64.1%)	0.828
Diarrhea	6 (13%)	10 (21.7%)	16 (17.4%)	0.271
Insomnia	2 (4.3%)	1 (2.2%)	3 (3.3%)	1.000
Restlessness/ tension	4 (8.7%)	3 (6.5%)	7 (7.6%)	0.694
Headache	5 (10.9%)	0 (0%)	5 (5.4%)	0.056

Adverse effects occurring were recorded over the period of 12 weeks in both the treatment arms. Nausea was the most common adverse effect in both the group (n=59) followed by diarrhea and headache (*n* = 6 and 5, respectively) in the Escitalopram group and diarrhea and tension/inner unrest (10 and 3, respectively) in the Vilazodone group. UKU scale was applied to evaluate and compare the adverse effects in both the groups of patients. Although the number of adverse effects was more in the Vilazodone group leading to higher score on UKU scale, the statistical analysis was not significant.

DISCUSSION

The classical treatment of depression has involved the initiation of treatment with a single antidepressant agent, and either switching or augmenting the existing regimen only if no response is observed after a period of 4–6 weeks of observation. However, evidences started emerging in the mid to late 2000s that initiating the antidepressant regimen with two drugs right from the beginning was seen to be associated with better response and lower remission rates [18].

This led to particular exploration of drugs which had more than one mechanism of action against depression in their pharmacological profile. Vilazodone is the result of such further experimentations as it combines the classical SERT inhibition with partial agonism at the 5HT1A receptors, which is seen in many atypical antipsychotics as well as the anxiolytic Buspirone [17].

The first randomized trials which showed the efficacy of Vilazodone in patients with depression were conducted by Rickels *et al.* [19] and Khan *et al.* [20]. Both these trials demonstrated superior efficacy of Vilazodone against placebo in patients with depression. This prompted further long-term trials to study the efficacy and tolerability of Vilazodone in depression.

In our study, the primary efficacy outcome was measured by the change from the baseline in the values on the HAM-D. HAM-D also known as HDRS is a multiple item questionnaire used to provide an indication of depression and as a guide to evaluate recovery [21].

Both Vilazodone and Escitalopram decreased HAM-D score at 1st, 2nd, 4th, and 12th week, but statistically significant difference was found during 1st (p=0.014) and 2nd week (p=0.001). HAM-D score was more effectively reduced with Vilazodone group.

Similar trend was observed in the study conducted by Kudyar *et al.* [7], where both the drugs decreased the HAM-D score significantly (p<0.0001), but, on comparison, Escitalopram was found better than Vilazodone.

Similarly, Vilazodone recently has also been shown to decrease HAM-D score in OPD patients presenting with MDD in a study by Mathews *et al.* [22], similar reduction in HAM-D score was also found in study conducted by Chauhan *et al.* [17] Bathla *et al.* [1] concluded no difference in efficacy between Vilazodone and Escitalopram probable reason for this difference may be smaller sample size and clinician rated usage of scales.

Secondary efficacy outcome measures of our study were HAM-A, MADRS, CGI-S, and CGI-I scales. HAM-A scores reduced from baseline in both Vilazodone and Escitalopram, at 1st, 2nd, 4th, and 12th week, the reduction was statistically significant during 2nd and 4th week. On comparison, Vilazodone is more efficacious in causing a decrease in the HAM-A score than Escitalopram.

Recent studies on Shi *et al.* [23] have also documented the drug to cause improvement in the HAM-A scores. Gommoll *et al.* [24] investigated the efficacy, safety, and tolerability of Vilazodone for generalized anxiety disorder in 395 patients found that Vilazodone showed significant superior efficacy over the placebo in mean changes on HAM-A from baseline to the end of double-blind treatment. Probable reason for this may be Vilazodone's dual mechanisms of action, which have been found useful in treating Generalized anxiety disorder (GAD), it has been long been speculated that Vilazodone could be effective in patients with GAD [25]. Hence, Vilazodone has also role in treating anxiety disorder along with depression. However, study conducted by Kudyar *et al.* [7] found that Escitalopram is more efficacious in decreasing HAM-A score compared to Vilazodone; however, no similar literature is available in review of literature.

Our study also showed reduction MADRS scores in both Vilazodone and Escitalopram group, there was significant reduction from week 1 (p=0.001) also there is score reduction at 2nd week (p=0.002), and 4th week (p=0.002). This finding was consistent with study conducted by Chauhan *et al.* [17] Khan *et al.* [26] published a report on analyzing the effectiveness of Vilazodone against the different symptoms of depression. They reported that statistically significant improvement was seen as early as week 1 after initiating treatment with Vilazodone (p<0.01).

The CGI-S can broadly capture additional dimensions that contribute to disease severity such as patient distress, functional impairment, and quality of life [27]. Both drugs showed improvement in secondary and additional efficacy measures with improvement across diverse outcome including reduced disease severity and clinical global improvement [22].

Both drugs showed statistically significant improvement in CGI-S score at 1st week and 2nd week of treatment and improvement in CGI-I score at 2nd and 4th week of treatment. Robinson *et al.* [28] conducted a multicentric study at 52 different centers in the US on patients with MDD. The study showed that clinical improvement in depressive symptoms was seen across MADRS, CGI-S, and CGI-I. According to a placebo controlled trial conducted by Croft *et al.,* [29] primary efficacy outcomes of Vilazodone using MADRS and CGI-S were significantly better than those in the placebo group (p<0.00001, effect size=0.54).

The finding Vilazodone has rapid onset of action was seen in our study when it showed statistically significant reduction in scores as early as 1 week in HAM-D (p=0.014), MADRS, (p=0,001), and CGI-S, (p=0.042) scales. Chauhan *et al*. also found significant reduction in week 1 values of MADRS scores in patients belonging to the Vilazodone group as compared to the other groups [17].

Safety was evaluated for the adverse drug reactions as demonstrated by the UKU scale. Although numerically Escitalopram was better tolerated than Vilazodone, statistic application did not reveal any superiority of Escitalopram. Gastrointestinal adverse event incidence in the present study is consistent with recent study on Vilazodone by Kudyar *et al.* [7] similar to prior studies [29] most instances of Vilazodone-related diarrhea and nausea were mild or moderate in intensity.

CONCLUSION

The present study demonstrated clinical advantage of use of Vilazodone over Escitalopram on HAM-D, HAM-A, MADRS, CGI-S, and CGI-I scores

in patients with MDD. Significant reduction in scores was seen as early as 1 week in Vilazodone group which justifies its early onset of action and superiority over SSRI which have average of 2 weeks delay in onset of action. This relatively faster onset of antidepressant action with Vilazodone can be useful in treating severe depression, especially in those associated with suicidal tendencies and can thus be useful in achieving response and remission in patients suffering from depression. HAM-A scale showed reduction in score significant in Vilazodone group which suggests that Vilazodone can also be used in patients with generalized anxiety disorder or depression patients with anxiety. Probable reason being Vilazodone's dual mechanisms of action of 5-HT reuptake inhibition and 5-HT1A partial agonism. This clinical advantage is absent in SSRIs. UKU scale demonstrated that among the adverse effects incidence of gastrointestinal adverse events was more with Vilazodone, though it was not statistically significant. Most instances patient had nausea vomiting and diarrhea and were mild or moderate in intensity. However, clinical superiority of one drug over the other can only be confirmed with further large studies.

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AUTHORS CONTRIBUTIONS

Rohini D Ankushe: Designed the study, collected, and analyzed the data. Vinod S Deshmukh: Contributed to study design, write up, and editing the manuscript. Ashish H Chepure: Helped in data collection. Jugalkishore B Jaju: Helped in supervision and review of manuscript.

CONFLICTS OF INTEREST

Nil.

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