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RESEARCH ARTICLE

Comparison of efficacy and safety of escitalopram and vilazodone in major depressive disorder

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ABSTRACT

Background: Major depressive disorder (MDD) is a worldwide prevalent psychiatric ailment associated with significant morbidity and mortality. Escitalopram is an effective selective serotonin reuptake inhibitor (SSRI), and vilazodone is a newer SSRI and partial serotonin receptor agonist approved for MDD. **Aims and Objectives**: The aim was to evaluate and compare the efficacy and safety of escitalopram and vilazodone in patients of MDD. **Materials and Methods**: The present, randomized study was conducted in a tertiary care teaching institute, and 50 patients between 18 and 55 years of either sex diagnosed with MDD based on Diagnostic and Statistical Manual of Mental Disorders Fifth Edition criteria were included in the study. Patients were assigned randomly into two groups to receive orally either escitalopram (10 mg) or vilazodone (20 mg) and baseline scores of Hamilton Anxiety Scale (HAM–A) and Hamilton Depression Rating Scale (HAM-D) were recorded. These were then assessed at 6 weeks for post-drug scores and compared with baseline using Mann–Whitney and Wilcoxon signed-rank test statistical analytic method. Intergroup comparison was also done. **Result**s: Average age of the patients taken was 39.74 ± 8.6 years with a male:female ratio of 19:31. The HAM-D score was significantly lowered by both escitalopram and vilazodone ($P < 0.0001$). HAM-A score was also similarly lowered by escitalopram ($P < 0.0001$) and vilazodone ($P < 0.0001$). On intergroup comparison, escitalopram was found to cause more lowering of HAM-D score and HAM-A score than vilazodone ($P < 0.0001$). Biochemical profile (blood sugar, serum urea, creatinine, hemoglobin, and total leukocyte counts) was not altered with either of the drugs over 6 weeks. No significant adverse drug reactions were noted with the drugs. **Conclusion**: Both drugs are effective in decreasing depression and anxiety scores in patients of MDD. On comparison, escitalopram was found better than vilazodone.

KEY WORDS: Depression; Anxiety; Selective Serotonin Reuptake Inhibitor; Escitalopram; Vilazodone; MDD

INTRODUCTION

Depression is a common mental disorder that leads to an impairment in the individual's ability to take care of his/her everyday responsibilities.[1] It affects nearly 121 million people worldwide. By the year 2030, it is proposed to be the leading cause of disability in the industrialized countries.[2] According to the WHO report in February 2017, the prevalence in India is 1.8%–39.6%. Major depressive disorder (MDD) is a disabling illness associated with significant impairment in physical and social functioning as well as increased morbidity and mortality.[3] It is characterized by clear-cut changes in effect, cognition, and neurovegetative functions with inter episode remissions for at least 2 weeks according to the Diagnostic and Statistical Manual of Mental Disorders Fifth Edition (DSM-5).[4] MDD is marked by the symptoms of depressed mood and

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loss of interest and pleasure. In addition, five or more of the symptoms should be present during the 2-week period which include significant weight loss, insomnia, fatigue or loss of energy, feelings of worthlessness, lack of concentration, and suicidal ideation. These symptoms may also be accompanied by the complaints of anxiety by the patient, somatic complaints such as bodily aches and pains and irritability. MDD accounts for 10–14% of patients seen by primary physicians worldwide.[5]

According to the American Psychiatry Association Guidelines, the treatment protocol for MDD may include pharmacotherapy, psychotherapy, somatic therapies such as electroconvulsive therapy (ECT), transmagnetic stimulation, or light therapy. Of these, antidepressant medications are the most widely used and accepted modality of treatment.

In the past, the first generation of antidepressants including monoamine oxidase inhibitors and tricyclic antidepressants was the preferred first-line drugs in MDD. Off late, due to the side effect profile of these two drugs, they are no longer the first-line drugs. Despite the current availability of different types of antidepressants, many patients do not attain adequate remission after treatment and may be accompanied with adverse reactions and non-compliance. Selective serotonin reuptake inhibitors (SSRIs) are drugs of choice in the treatment of MDD.[6,7] Citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, and sertraline are the commonly used SSRI. A large body of literature supports the superiority of SSRIs compared with placebo. Although all the SSRIs exert their action by modulating serotonin reuptake, they differ in their pharmacologic profiles which may influence their efficacy and tolerability in individual patients.

Escitalopram, the S-enantiomer of citalopram, 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 the highest probability of remission.[8] A meta-analysis suggests a superiority of escitalopram as compared to other SSRIs.[9] The use of escitalopram may be associated with adverse effects such as sexual dysfunction, somnolence, and dose-dependent QT prolongation.[10] It is a known inhibitor of the enzyme CYP2D6 which may lead to impaired metabolism of many drugs such as tamoxifen advocating their cautious use.

Vilazodone is a new antidepressant with a unique mechanism of action whereby it simultaneously acts as an SSRI and a 5 HT_{1A} receptor partial agonist.[11] It was approved in 2011 for the treatment of MDD in adults.[12] Data from phase 2 and phase 3 trials suggest that vilazodone is effective in the dose of 20–40 mg for the treatment of MDD. Due to its dual mechanism, it combines the serotonin reuptake inhibition, and anxiolytic mechanism can be used as an effective and well-tolerated class of drug for patients with MDD.[13,14] Nevertheless, there is a dearth of knowledge about the complete aspects of usage and outcomes of the drug.

Although both the drugs are being used in the current clinical practice, to the best of our knowledge, there is no study cited to compare the two drugs. Hence, this study was done with the objective to evaluate and compare the efficacy and safety of both the drugs escitalopram and vilazodone in MDD to address the superiority of one over the other. Hamilton Anxiety Scale (HAM–A) and Hamilton Depression Rating Scale (HAM–D) scales have been used to evaluate and compare the two. These are the most widely used scales for depression and anxiety in clinical research and are easier to apply and interpret for the purpose of this study done at a smaller scale. They include a wide range of components to assess the symptoms in the patients of MDD. This study would of great help to the treating clinicians and the public as a whole to choose a better treatment option.

MATERIALS AND METHODS

The present preliminary randomized (by block permutation method) open-label study was conducted in the Department of Pharmacology and Therapeutics in collaboration with the Department of Psychiatry, Government Medical College, Jammu, over 6 months, i.e., from December 2015 to June 2016 after approval of IEC vide no I_{64} B/C/2015/262.

A total of 50 patients from the psychiatry outpatient department (OPD) diagnosed with major depression by the psychiatrist were included in the study after they fulfilled the inclusion criteria. A written informed consent was obtained from legal guardian after explaining the nature & purpose of the study.

The inclusion criteria were: (1) Patients of either sex, (2) age between 18 and 55 years, and (3) newly diagnosed patients who meet the DSM 5 criteria for depression.[4] The essential feature of MDD is a period of at least 2 weeks depressed mood or the loss of interest and pleasure in nearly all daily activities. The patient must also have at least five additional symptoms from change in appetite, weight, sleep, psychomotor activity, decreased energy, feeling of guilt, ideas of death, and suicidal ideation as per the DSM V criteria for depression.

The exclusion criteria for the study were as follows: (1) Severe comorbid conditions such as diabetes, hypertension, and ischemic heart disease, (2) patients taking antidepressants in the past 6 weeks, (3) pregnant or lactating females, (4) intake of other drugs for psychosis or anxiety, (5) history of substance abuse, (6) any chronic ailment or drug intake leading to depression, (7) patients with neurological disorders such as stroke, dementia, or seizures, and (8) any history of allergy to the drugs.

Selected patients were assigned randomly to receive either escitalopram (10 mg) or vilazodone (20 mg) once daily. 26 patients were included in the escitalopram group and

24 patients in the vilazodone group. The total duration of treatment for the study was 6 weeks.

At the baseline, parameters such as blood pressure both systolic and diastolic were noted, along with the height and weight of the patients. Blood sugar levels, total leukocyte counts (TLC), serum urea, serum creatinine, and hemoglobin were estimated. All these variables were monitored over the period of the study at the 3rd week as well as the 6th week.

The primary efficacy outcomes were the change from the baseline in the values on the HAM-D as well as the HAM-A. HAM-D also known as hamilton depression rating scale (HDRS) is a multiple item questionnaire used to provide an indication of depression and as a guide to evaluate recovery.[15] The original version contained 17 items and designed for adults to rate the severity of their depression based on mood, feelings of guilt, suicide ideation, insomnia, anxiety, weight loss, and other somatic symptoms. The HSRD-21 is a 21-item HAM-D scale which was used in the current study to evaluate the patients' symptoms of depression.[16] Each item on the questionnaire is scored on a 3 or 5 point scale, and depending on the item, the total score is calculated. A score of 0–7 is normal, scores 8–13 indicate mild depression, 14–18 indicate moderate depression, 19–22 indicate severe depression, and >23 indicate very severe depression.

HAM-A scale is a psychological questionnaire developed to measure patient's symptoms of anxiety.[17] It includes 14 parameters including anxious mood, tension, fears, insomnia, somatic complaints, and behavior at the time of the interview. Each item is scored from 0 to 5 based on the severity of the symptom. The total score is calculated for all the items.

Both HAM-D and HAM-A scales were assessed at baseline, 3rd week, and 6th week in both groups of patients in the study.[18]

Adverse events due to both the drugs were monitored using the Udvalg for Kliniske Undersogelser (UKU) scale, i.e., The UKU Side Effect Rating Scale.[19] It is a clinician-rated scale with well-defined items developed to provide a comprehensive rating of side effects with psychopharmacological medications.

Statistical Analysis

The evaluation of patients in both the groups was done by applying the HAM-D and HAM-A scales and reported as the mean ± standard deviation as well as the median values. The analysis was performed using SPSS 16 Software. The change in the scores from baseline was noted and assessed by the use of Wilcoxon signed-rank test, while intergroup comparison between two groups was done by Mann–Whitney test. All the parameters including the blood and biochemical evaluation were compared with the baseline using the unpaired *t*-test. A $P < 0.05$ was considered statistically significant. The evaluation was done on intention to treat basis.

70 patients were screened for the study participation, of these 50 patients fulfilled the inclusion and exclusion criteria. On randomization and allocation to two groups, 26 patients were included in the escitalopram group and 24 in the vilazodone group. All the patients were followed up over 6 weeks and analyzed at the end of the study [Figure 1].

RESULTS

Of the 70 patients screened, 50 patients were included in the study who met the inclusion as well as the exclusion criteria. In both the groups, the demographic profile was noted along with systolic and diastolic blood pressure, height, and weight. Blood sugar levels, TLC counts, serum urea, creatinine, and hemoglobin levels were done at baseline, 3 weeks, and 6 weeks. On intergroup comparison, no significant difference was seen [Table 1].

On treatment with the drugs escitalopram and vilazodone, Hamilton-D scores were calculated at the baseline and over 6 weeks. On evaluation in intergroup comparisons, there was statistically significant difference at 3 weeks ($P < 0.05$), whereas at 6 weeks, the difference was extremely statistically significant ($P < 0.0001$) [Table 2].

On treatment with the drugs escitalopram and vilazodone, Hamilton-A scores were calculated at the baseline and over 6 weeks. On evaluation in intergroup comparisons, there was statistically significant difference at 3 weeks ($P < 0.001$), whereas at 6 weeks, the difference was extremely statistically significant ($P < 0.0001$) [Table 3].

Adverse effects occurring were recorded over the period of 6 weeks in both the treatment arms. Nausea was the most common adverse effect in both the groups ($n = 4.9$), followed by diarrhea and headache ($n = 4$) in the escitalopram group and palpitations and insomnia ($n = 5$) 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. [Tables 4 and 5].

DISCUSSION

With the best of efforts, we could not find any studies comparing escitalopram which is the most accepted drug with the recent drug vilazodone in outdoor patients of MDD. The present study was therefore conceived to compare these two drugs in OPD patients of MDD for their efficacy and safety.

Our results entailing the demographic profile revealed that most patients were between 39.74 and 8.6 years.

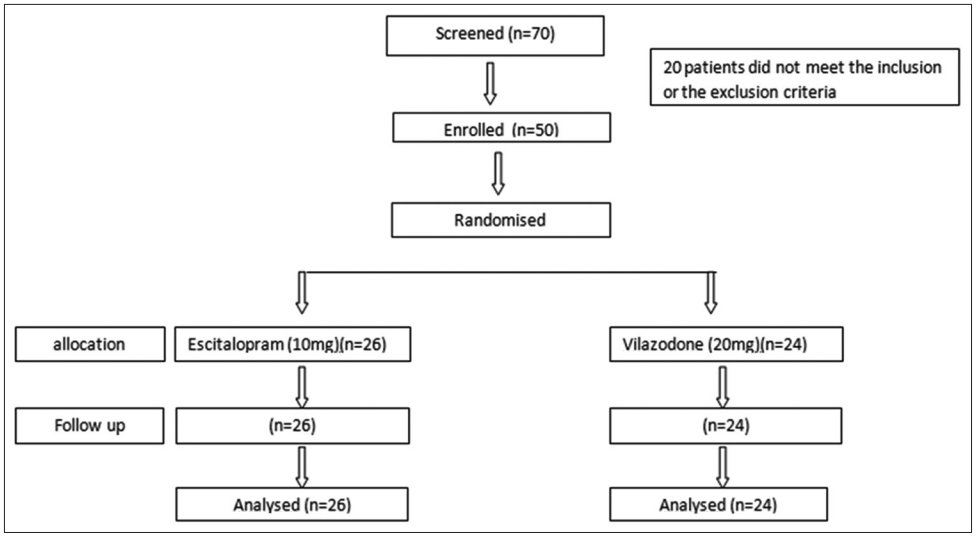

Figure 1: Study flowchart

Table 1: Baseline profile and effect of escitalopram and vilazodone treatment on biochemical parameters

Parameters	Duration (weeks)	Mean+SD		*P* (unpaired *t*-test)
		Escitalopram (*n*=26)	Vilazodone (*n*=24)	
Age (years)	0	37.25	41.36	
Male: Female	0	1:1	3:4	
Blood pressure (SYS) mmHg	0	129±6.24	130.57±4.47	0.315
Blood pressure (diastolic)	0	83.38±6.84	85.86±5.75	0.1735
Weight (kg)	0	68.69±10.30	69.71±11.40	0.741
Height (cm)	0	166.28±4.72	165.64±6.95	0.640
Blood sugar (mg)	0	91.13±7.37	92.71±7.2	0.44
	3	92.1±7.8	91.63±7.3	0.82
	6	91.2±7.6	91.56±7.5	0.86
TLC (mm^3)	0	7793±1059	7842±1132	0.87
	3	7867±1089	7786±1098	0.79
	6	7876±1125	7765±1087	0.72
Serum urea	0	28.06±2.59	28.29±2.89	0.76
	3	29.04±2.4	22.98±2.63	0.14
	6	29.01±2.3	27.86±2.63	0.10
Serum creatinine	0	0.873±0.06	0.851±0.07	0
	3	0.87±0.08	0.831±0.09	0.1
	6	0.85±0.09	0.878±0.08	0.41
Hb (g)	0	10.22±0.80	10±0.43	0.23
	3	10.23±0.89	10.43±0.89	0.30
	6	10.13±0.79	10.34±0.35	0.23

*P<0.05, **P<0.01, ***P<0.001. SD Standard deviation, TLC: Total leukocyte counts, Hb: Hemoglobin

Females outnumbered males in the current study as the ratio between males and females was 19:31. The HAM-D scores calculated during the study were significantly lowered by both escitalopram and vilazodone ($P < 0.0001$). HAM-A scores were also similarly lowered by escitalopram ($P < 0.0001$) and vilazodone ($P < 0.0001$). However, on intergroup comparison, escitalopram was found to cause more lowering of HAM-D score and HAM-A score than vilazodone ($P < 0.0001$).

Jiang *et al*., 2017, and Kishi *et al*. 2017 in their respective randomized controlled trials revealed a similar trend in the age group of patients suffering from MDD as concluded by our study.[20,21] In a prospective, observational study on 523 patients, Kuga *et al*. 2017 reported that more number of females were receiving treatment with SSRI as compared to males which are in agreement with our results.[22]

Table 2: Effect of treatment of escitalopram and vilazodone on HAM-D scores

Duration (weeks)	HAM-D scores					
	Escitalopram		Vilazodone		Mann–Whitney U (Z value)	*P*
	Mean±S.D	Median	Mean±S.D	Median		
0	10.69±1.35	10	11±1.52	11	−1.436	0.151
3	8.51±1.43***	8	9.29±1.14***	9.5	−2.709	0.07*
6	6.06±0.93***	6	8.29±0.9***	8	−5.361	<0.0001***

*P<0.05, **P<0.01, ***P<0.001, SD: Standard deviation, HAM-D: Hamilton Depression Rating Scale

Table 3: Effect of treatment of escitalopram and vilazodone on HAM-A scores between groups

Duration (weeks)	HAM-A scores					
	Escitalopram		Vilazodone		Wilcoxon signed-rank test (Z value)	*P*
	Mean±S.D	Median	Mean±S.D	Median		
0	19.06±1.73	19	19.08±1.83	19	−0.240	0.811
3	16.50±1.10***	16	17.61±1.36***	18	−2.933	0.003**
6	14±1.10***	14	16.43±0.94***	16.5	−5.606	<0.0001***

*P<0.05, **P<0.01, ***P<0.001, SD: Standard deviation. HAM–A: Hamilton anxiety scale

Table 4: Adverse effects across both groups of escitalopram and vilazodone

Side effects	Escitalopram (n=26)	Vilazodone (n=24)
Nausea	4	9
Vomitting	2	–
Diarrhoea	4	–
Palpitations	3	5
Sexual dysfunction	1	–
Loss of appetite	1	–
Insomnia	3	5
Constipation	1	–
Dry mouth	–	5
Restlessness	–	2
Headache	4	2
Giddiness	1	3

Table 5: Effect of treatment of escitalopram and vilazodone on UKU scale

Parameter	Escitalopram	Vilazodone	*P*
UKU mean±S.D	0.93	1.13	0.24

SD: Standard deviation, UKU: Udvalg for Kliniske Undersogelser

HAM-D score which is an indicator of depression has a significant role in assessing the improvement or deterioration of the disease. Both the drugs in the current study decreased the HAM-D score significantly in similar fashion ($P < 0.0001$). Urade *et al*. 2015 have also demonstrated that escitalopram is efficacious in causing a decline in HAM-D score.[23] Similarly, vilazodone recently has also been shown to decrease HAM-D score in patients of OPD patients presenting with MDD.[24] However, when escitalopram and vilazodone were compared, it revealed that the HAM-D score was significantly and more effectively reduced with escitalopram than with vilazodone at 3 weeks ($P = 0.03$) and 6 weeks ($P < 0.001$).

HAM-A score is suggestive of the anxiety component in the patients of MDD. Results of the present study revealed that escitalopram caused a decrease in the HAM-A scores during the entire phase of the study spanning 6 weeks. ($P < 0.0001$). Vilazodone also caused a decrease in the HAM-A scores up to 6 weeks. ($P < 0.0001$). Recent studies on vilazodone by Shi *et al*. 2016 have also documented the drug to cause improvement in the HAM-A scores.[25] However, the comparison of escitalopram and vilazodone suggested that escitalopram is more efficacious in causing a decrease in the HAM-A scores as compared to vilazodone, ($P < 0.0001$). In our review of literature, we failed to find any such similar report citation.

Safety was evaluated by 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.

Results of the current trial have clearly demonstrated that escitalopram is more efficacious than vilazodone in targeting both the anxiety and depression component of MDD. This suggests the superiority of escitalopram over recent drug vilazodone. This was a preliminary study done in a single-center setup with less number of patients; the results of which point toward the more advantageous use of escitalopram as compared to vilazodone. Furthermore, being an open-label study, no blinding was done for the evaluation of both the drugs. Hence, further research with greater number of participants and application of more scales to evaluate the effects of drugs in MDD is required to confirm the superiority of one over the other.

CONCLUSION

The current preliminary study demonstrates toward the clinical advantage of the use of escitalopram over vilazodone on the HAM-D and HAM-A scores in patients of MDD. However, the clinical superiority of one over the other can only be confirmed with further larger studies.

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