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Original Research Article

A prospective study to compare the efficacy of vilazodone and escitalopram tablets in the treatment of patients with newly diagnosed major depressive disorder

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ABSTRACT

Background: With the availability of large number of anti-depressant drugs, a thorough knowledge of comparative efficacy of the commonly used antidepressants is necessary to prescribe best drug molecule to the patient. This improves the compliance and therapeutic outcome. The aim of the study is to compare the efficacy of vilazodone and escitalopram in the treatment of patients with newly diagnosed major depressive disorder in a prospective study.
Methods: 200 patients attending the psychiatry out-patient department diagnosed with major depressive disorder were assessed and enrolled into vilazodone 40 mg and escitalopram 20 mg treatment groups. Hamilton depression rating scale score (HDRS) was used to assess the severity of depression disorder at regular intervals.
Results: Maximum cases were in the 21-30 age group and minimum cases in above 60 years age group. Males contributed maximum to number of depression cases with respect to females in both the treatment groups. Both escitalopram and vilazodone therapy group showed onset of improvement at the end of 1st week. The efficacy of both treatment arms in reducing HDRS is comparable till 2nd week of treatment, but at 6th month vilazodone was more efficacious than escitalopram therapy.
Conclusions: Escitalopram tablet given once/twice daily is significantly effective in reducing HDRS score as early as 2nd week. At 6th month vilazodone tablet was more efficacious than escitalopram therapy. Vilazodone is safe with fewer adverse effects as compared to escitalopram.

Keywords: Anti-depressants, Vilazodone, Escitalopram, Major depressive disorder

INTRODUCTION

Depression is a mental illness characterized by persistent sadness and loss of interest in activities that one normally enjoys, with inability to carry out daily activities, for at least 2 weeks duration.[1] More than 300 million people are affected by mental depression. About 8 lakh people die due to suicide associated with depression every year.[2] Depression is found to be the 4th most urgent health disorder worldwide.[3] Major depressive disorder (MDD) is a crucial health and economic burden, with an annual cost of $98.9 billion.[4] Depression is more common in females as compared to males. Genetic influences have a greater association with the onset of mood disorder and suicide.[5] Risk factors for depression are family history of depression, physical illness, medications and stress factors. It is also seen that stressful life events were specifically more in the elderly females and those with lower per capita income.[6] Other variants of depression are recurrent depressive disorder, bipolar affective disorder and persistent depressive disorder.[7-9] Recent studies show that the prevalence rates of depression are nearly twice in the urban areas.

Clinical features seen in depression are depressed mood, lack of energy, inability to feel pleasure, psycho-motor disturbances, pseudo-dementia, cognitive disturbances, mood congruent psychotic features, weight gain or loss, insomnia or hypersomnia, raised or low appetite and sexual dysfunction.[10] According to 'mono-amine hypothesis' of depression, the metabolites of nor-epinephrine (NE) and serotonin (5-HT) were found to be decreased in the body fluids of depressed patients. The drugs used in treatment of depression are seen to increase the amount of neuro-transmitter available at monoamine synapses. Various modalities of treatment of depression are cognitive behavioural therapy, medications, electroconvulsive therapy and yoga.[11,12] Various drugs used for the treatment of depression are Selective serotonin re-uptake inhibitors (SSRIs), Serotonin and nor-epinephrine reuptake inhibitors (SNRIs), Tricyclic antidepressants (TCAs), Mono amine oxidase inhibitors (MAO-I) and atypical anti-depressants.[13] SSRIs ease depression by increasing levels of serotonin by blocking the re-uptake of it in the brain. Various side effects are also associated with use of SSRIs which include sexual dysfunction due to stimulation of post synaptic 5-HT_2 receptors, possibly in the spinal cord, weight gain, sleep disturbances, agitation and diarrhoea.[14]

As per world health organization, depression is considered as the 4th leading cause of disability worldwide and it is predicted that soon depression will be the 2nd leading cause.[15] A few patients with major depression disorder might show features of manic episode like hyperactivity, lack of sleep, flight of ideas and this disorder is termed as bipolar depression.[16] Kendler et al, showed that major depression is heritable and it could be dependant or independent of factors to personality traits.[17,18]

Major depressive disorder is associated with high mortality, much of which is accounted for by suicide; however, it is not the only cause. Until recently, hypothalamic pituitary adrenal axis hyperactivity had been the most extensively investigated abnormality associated with major depressive episodes, which is effectively managed by SSRIs. Since it is important to compare efficacy of drugs with in various group of drugs viz. SSRIs, SNRIs, MAOIs and TCAs and no study has been done to compare efficacy between the vilazodone and escitalopram both SSRIs in Indian population. The present study therefore aims to compare the efficacy between the two drugs in newly diagnosed major depressive disorder cases.

METHODS

Study design

This study was conducted as a prospective study, comparative clinical study from February 2018 to June 2019 by the department of pharmacology in collaboration with the department of psychiatry at Uttar Pradesh university of medical sciences, Saifai, Uttar Pradesh. The study protocol was approved by the institutional review board of UPUMS, Saifai, Etawah with the ethical clearance number-38/2018. All patients of age 18-60 years age with 1st history of major depressive disorder were included in the study. Patients who were on medication for other illness, infections, other illness and past history of depression were excluded from the study. All the patients diagnosed with MDD meeting the DSMV criteria were included in the study. The total sample size of the study comprised of 200 patients including males and females. After obtaining written informed consent from the participants, structured interview schedule using Hamilton depression rating scale score questionnaire (HADSQ) was provided. We screened a total of 253 patients with major depressive disorder (121 patients in escitalopram treatment group and 132 patients in the Vilazodone treatment group); out of which 53 patients were excluded (53 patients stopped the follow-up criteria). Remaining 200 patients were randomized into 1:1 ratio and divided equally into two treatment arms comprising of 100 patients each. Group 1 was allocated to escitalopram medication while group 2 was allocated vilazodone medication. After establishing rapport with the patients, the purpose and procedure of the study were explained following which tablet vilazodone 40 mg/day or tablet escitalopram maximum 20 mg/day was given at bedtime. Each recruited patient's demographic details were noted and their telephone number was recorded. The Hamilton depression rating scale was applied to the individual patients. The HDRS score of the patient was noted on the day of enrolment, at the end of 1st week, 2nd week, 4th week, 8th week, 12th week and 6th month respectively.

Statistical analysis

The data is represented in mean±SD. The data is analysed by one-way ANOVA followed by Dunnett's test with 95 % level of confidence interval. P value <0.05 is considered as statistically significant.

RESULTS

Figure 1, depicts total patients in their respective age group. The gender-wise distribution in both the treatment arms is shown in Figure 2. Of the total 200 patients recruited for this study, 141 were males and 59 females, which got randomly distributed in group 1 and 2 treatment arms as 62, 79 (for males) and 38, 21 (for females). The age range of patients recruited for the study was 18-60 years, with mean age of all patients' 34.4±2.8 years. Group wise mean age was 33.61±4.24 and 35.14±12.72 years, with no significant difference between groups. Studies show that most of the cases of depression are seen in patients between 20 and 50 years age. In our study, males contributed to most of the cases of major depressive disorder which was opposite to the current research findings (stating that women are more affected). One of the reasons for male out numbering

females in our study could be attributed to small sample size. Maximum numbers of cases were in the age group 21-30 years.

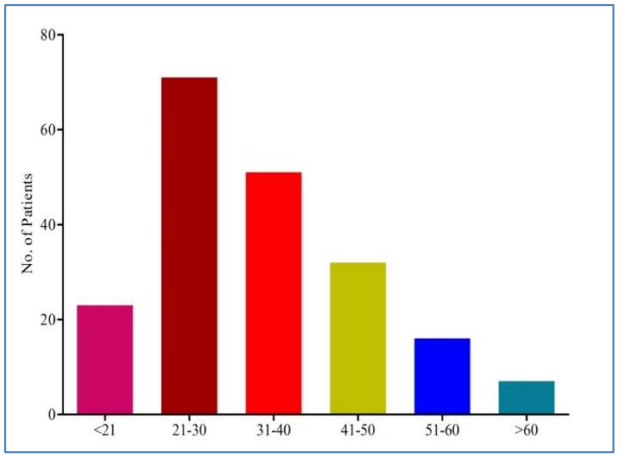

Figure 1: The relation between number of patients and the age group in depression.

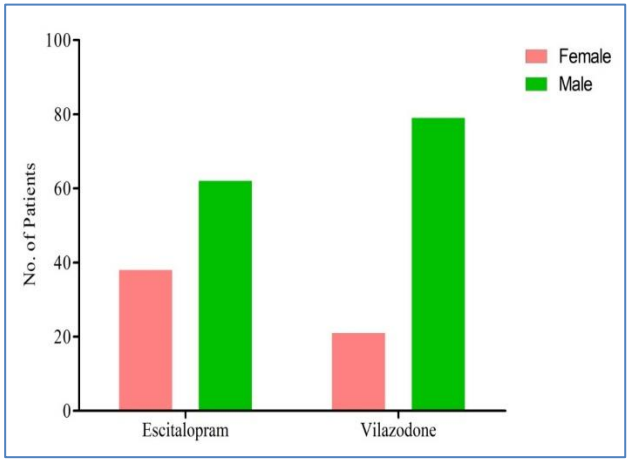

Figure 2: Gender wise distribution in both the treatment groups.

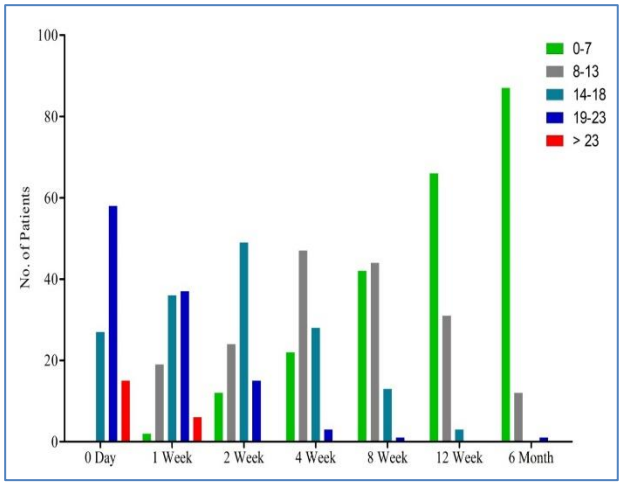

Figure 3: HDRS score in the escitalopram treated patients.

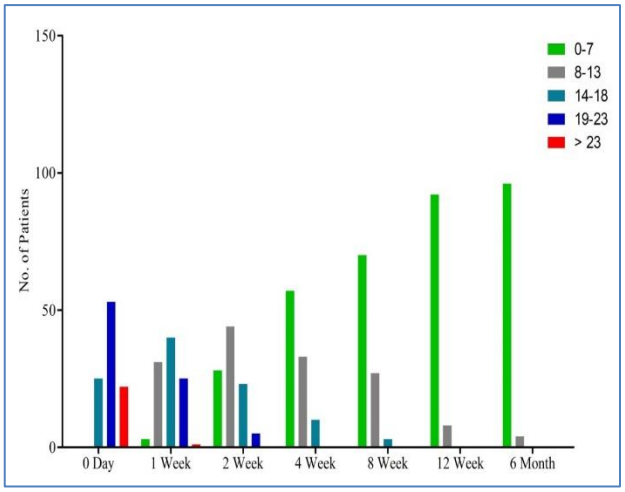

Figure 4: HDRS score in the vilazodone treated patients.

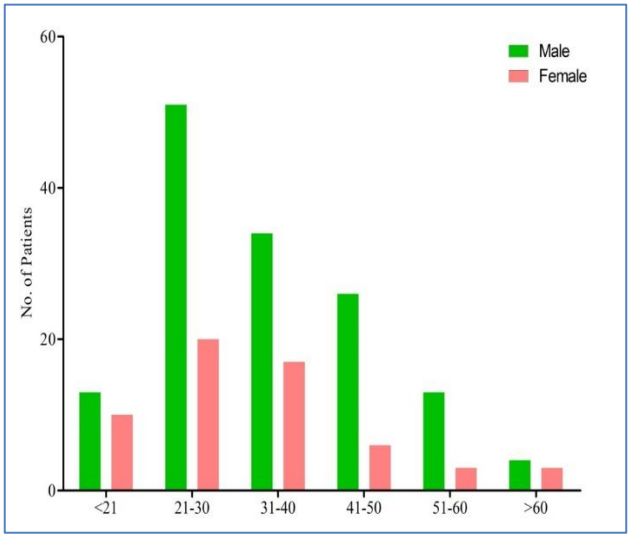

Figure 5: The relation of gender wise distribution with age-group.

The HDRS score in the escitalopram and vilazodone treated patients at various weeks are shown in the Figure 3 and 4. The HDRS scores of normal value obtained in the 1st week, 2nd week, 4th week, 8th week, 12th week and 6th month was 2%, 12%, 22%, 42%, 66%, 87 % in the escitalopram treatment group; and it was 3%, 28%, 57%, 70%, 92%, 96% in the vilazodone treatment group. They both were equally efficacious in reducing HDRS score till the 6th month of follow-up, but the vilazodone medication reduced HDRS score more as compared to escitalopram medication. Figure 5 shows the distribution of males and females in different age groups.

DISCUSSION

The aim of our study was to compare the efficacy of escitalopram and vilazodone in the treatment of major depressive disorder. We found that both treatment arms reduced HDRS significantly ($p<0.0001$) at 6th month in

escitalopram therapy and vilazodone therapy respectively. Significant reduction ($p<0.001$) of HDRS score in both the arms was observable as early as 2nd week visit. A study done by Eckert and Falissard shows that escitalopram is non-inferior to venlafaxine XR. Boulenger et al, showed that escitalopram was more effective than paroxetine in the treatment of major depressive disorder, in the long term course.[19] As per James Signorovitch et al, treatment of adult MDD patients with escitalopram was significantly more likely to result in remission without concurrent adverse events compared to treatment with current SNRIs. Burke and colleagues have proved superior clinical efficacy of escitalopram over citalopram in their studies.[20] Some of the few research studies done on vilazodone by Rickels et al, Khan et al, Jain et al, Croft et al and Mathews et al point out that vilazodone therapy had higher efficacy on comparison to placebo.[21] There are currently no head-to-head studies reported for vilazodone comparing efficacy against other antidepressant agents as well as no reported head-to-head studies comparing tolerability of vilazodone against other antidepressant agents. Robinson et al. conducted an open-label, placebo controlled study assessing the safety and tolerability of vilazodone in patients with major depressive disorder and found out that vilazodone 40 mg/day for 1 year was safe and well tolerated by adults with major depressive disorder with most frequent adverse effect reported being diarrhoea (35.7%), nausea (31.6%), and headache (20.0%).[22] More than 90% of these AEs were mild or moderate.

In a total of 200 newly diagnosed major depressive disorder patients in our study, a total of 63 (31.5%) developed adverse effect, of the total 63 patients, 52 were from escitalopram treatment arm and rest 11 from vilazodone treatment arm. The most commonly observed adverse effect in escitalopram treatment group was decreased concentration with 16 patients (16%) from escitalopram treatment group and diagnosed at 2nd week follow up interval. Another common adverse effect observed was nausea; seen in 14 patients. 12 patients had headache and 10 patients had insomnia.

In the vilazodone treatment arm, the major adverse effect seen was diarrhoea in 8 (8%) patients. There were 2 (2%) patients affected with nausea and 1 (1%) patient with somnolence. We believe that due to relatively small study duration we could not ascertain more adverse effect. The adverse reactions observed in our study were mild and not troublesome for the patients as they seldom reported it without leading questions.

There are few shortcomings of our study, our sample size was small. The ADRs obtained were not entirely passive and investigators had to ask leading questions to unearth them, thus a bias might be present. Another reason of bias could be due to the fact that our study was open label. A longer duration, blind study with larger sample size would be helpful in covering these shortcomings.

CONCLUSION

Escitalopram tablet given once/twice daily is significantly effective in reducing HDRS score as early as 2nd week with 87% recovery at the end of study. Vilazodone tablet given once/twice daily is also significantly effective in reducing HDRS score as early as 2nd week. At 6th month vilazodone tablet was more efficacious than escitalopram therapy. Vilazodone offered 96% recovery to the patients. Adverse effects were more commonly observed in escitalopram treatment group as compared to vilazodone.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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