International Journal of Advances in Medicine
*Arya N et al. Int J Adv Med. 2020 Apr;7(4):643-649*
http://www.ijmedicine.com
pISSN 2349-3925 | eISSN 2349-3933
DOI: http://dx.doi.org/10.18203/2349-3933.ijam20201116

**Original Research Article**

# A comparative prospective open label randomized controlled 8 week study in patients of depression treated with vilazodone and sertraline

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**Received:** 31 January 2020
**Revised:** 13 February 2020
**Accepted:** 28 February 2020

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## ABSTRACT

**Background:** Depression is a mood disorder treated with various antidepressant such as SSRIs due to lesser toxicity and improved safety profile.
**Methods:** This was an eight week randomised active controlled parallel group study. 54 patients were allocated in two group. Group A received vilazodone while group B received sertraline. Assessment done at baseline, 2, 4 and 8 weeks on the basis of clinical efficacy, sexual dysfunction, side effects and weight gain using Hamilton Depression Rating Scale (HAM-D), Hamilton Anxiety Rating Scale (HAM-A), Arizona Sexual Experience Scale (ASEX) and UKU Side Effect Rating Scale.
**Results:** HAM-D score of group A was 18.78±1.78 and 7.67±1.66 while in group B was 19.04±2.12 and 8.15±1.77 at baseline and 8 weeks respectively. HAM-A score of group A was 15.44±1.50 and 6.63±1.39 while in group B was 15.26±1.83 and 7.07±1.14 at baseline and 8 weeks. ASEX total score of group A was 15.63±1.28 and 14.63±1.33 while group B was 15.52±1.37 and 16.41±1.12 at baseline and 8 weeks. ASEX desire score of group A was 9.63±0.93 and 8.67±0.88 while of group B was 9.59±0.93 and 10.07±0.92 at baseline and 8 weeks. UKU side effect rating at 2 and 8 weeks of group A was 0.22±0.42, 1.04±0.76 while in group B was 0.37±0.49, 1.89±0.85.
**Conclusions:** Vilazodone and Sertraline are equally efficacious in treatment of depression and associated anxiety. When side effect profile were compared Vilazodone is found superior to Sertraline.

**Keywords:** Anxiety, Depression, Sertraline, Sexual dysfunction, Vilazodone

## INTRODUCTION

Depression is a major public health problem with significant morbidity and disability as well as socioeconomic impact. Approximately 17% of the population is affected with depression during their life time.[1]

The most commonly prescribed antidepressants are the SSRIs and SNRIs due to their lesser toxicity and improved safety profile than TCAs.[2] Hence antidepressant with better efficacy and lower side effects are required for treatment.[3]

Vilazodone is a novel SSRI having 5HT1A receptor partial agonistic activity. It was approved in 2011 by US FDA for the treatment of major depressive disorders.[4,5] Sertraline is a well-established SSRI and widely used for the treatment of major depressive disorder, common adverse effects are gastrointestinal disturbances, anxiety, sexual dysfunction and impaired cognition.

The study was planned with objective to compare the clinical efficacy and occurrence of sexual dysfunction in patients treated with Vilazodone and Sertraline.

## METHODS

An eight week randomised active controlled parallel group study conducted in patients of depression. Study duration was September 2018 to September 2019. Approval was obtained from the Institutional Ethics Committee of King George's Medical University, U.P., Lucknow (Ref. Code: 93rd ECM II B-Thesis/P16).

Study unit involves Patient from adult psychiatric OPD of K.G.M.U., Lucknow.

In drug therapy study patients were randomised into group A and group B by a computer generated randomization table. Patients in group A were given vilazodone and patients in group B were given sertraline.

Vilazodone was administered orally at a dose of 10 mg H.S for 7 days, raised to 20 mg once daily from 8th day. The dose was increased to maximum of 40 mg per day after 2 weeks, if required and tolerated by the patient.

Sertraline was administered orally at a dose of 50 mg H.S for 14 days. The dose was increased to a maximum of 100 mg per day after 2 weeks, if required and tolerated by the patient.

### *Inclusion criteria*

- Patients with diagnosis of Depression as per International Classification of Disease-10, DCR.
- Patients aged between 18 to 50 years.
- Married and in stable sexual relationship with the partner for last 6 months.
- Patient willing to sign the written informed consent were included in the study.

### *Exclusion criteria*

- Patient with any comorbid psychiatric disorder, except tobacco use disorder.
- Patient requiring the use of other psychotropic medication except specified medications and rescue medication.
- Patients having any major medical/surgical illness or any clinically significant abnormality in baseline investigations.
- Pre-existing sexual dysfunction independent of depression were excluded from the study.

### *Criteria for drop out*

- Appearance of severe side effects that required management with other drugs.
- Withdrawal of consent.

### *Assessment tools*

- Semi Structured Proforma for recording socio-demographic profile and clinical variables of the patient, designed for the study.
- HAM-D (Hamilton Depression Rating Scale)[6]
- HAM-A (Hamilton Anxiety Rating Scale)[7]
- ASEX (Arizona Sexual Experience Scale) [8]
- UKU (Udvalg for Kliniske Undersogelser) Side Effect Rating Scale[9]

Rescue Medications used were zolpidem upto 10 mg/day for insomnia and etizolam upto 2 mg/day for anxiety.

### *Statistical analysis*

Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean±SD. Quantitative variables were compared using Unpaired t-test between two groups.

Paired t test was used for comparing pre and post variables for scale parameters. Qualitative variables were compared using Chi-Square test /Fisher's exact test as appropriate. A p-value of <0.05 was considered statistically significant.

## RESULTS

Total 102 patients were screened for the study. Out of them 48 patients did not fulfil selection criteria. The remaining 54 patients who were included in the study were allocated to either group A or B by block randomization table generated from computer. Each group included 27 patients.

### *Last Observation Carried Forward (LOCF)*

Applied for 5 patients. Two patients from group A and three patients from group B; three patients (one from group A and two from group B) had completed first follow up visit. Two patients (one from group A and one from group B) had completed two follow up visit out of three.

### *Socio-demographic characteristics*

The socio-demographic characteristics of two groups are summarized in Table 1. Demographic characteristics of two groups were compared at baseline by Chi-square test and Fisher value test which showed no significant difference between the groups.

### *Clinical variables*

Clinical variables of group A and B are summarized in the Table 2. No significant difference was seen in past, personal and family history.

**Table 1: Socio-demographic characteristics of study group.**

| Parameters | Group A (N=27) | Group B (N=27) | p-value |
|---|---|---|---|
| Age groups | | | |
| 22-30 years | 7(25.9) | 8(29.6) | 0.948 |
| 31-40 years | 13(48.1) | 12(44.4) | |
| 41-50 years | 7(25.9) | 7(25.9) | |
| Mean Age | 34.93 | 35.22 | 0.889 |
| Gender | | | |
| Male | 14(51.9) | 14(51.9) | 1.000 |
| Female | 13 (48.1) | 13(48.1) | |
| Marital status | | | |
| Married | 27(100) | 27(100) | NA |
| Unmarried | 0(0) | 0(0) | |
| Religion | | | |
| Hindu | 25 (92.6) | 22 (81.5) | 0.420# |
| Muslim | 2 (7.4) | 5 (18.5) | |
| Education | | | |
| Illiterate | 9 (33.3) | 5 (18.5) | 0.627 |
| Junior | 4 (14.8) | 8 (29.6) | |
| High school | 5 (18.5) | 5 (18.5) | |
| Intermediate | 3 (11.1) | 5 (18.5) | |
| Graduate | 5 (18.5) | 3 (11.1) | |
| Post graduate | 1 (3.7) | 1 (3.7) | |
| Family Type | | | |
| Nuclear | 17 (63.0) | 15 (55.6) | 0.580 |
| Joint | 10 (37.0) | 12 (44.4) | |
| Occupation | | | |
| Farmer | 4 (14.8) | 6 (22.2) | 0.959 |
| Labour | 4 (14.8) | 3 (11.1) | |
| Housewife | 12 (44.4) | 12 (44.4) | |
| Unemployed | 6 (22.2) | 5 (18.5) | |
| Service | 1 (3.7) | 1 (3.7) | |
| Family income | | | |
| <10,000 | 15 (55.6) | 14 (51.9) | 0.954 |
| 10,000-20,000 | 8 (29.6) | 9 (33.3) | |
| >20,000 | 4 (14.8) | 4 (14.8) | |
| Not present | 20 (74.1) | 16 (59.3) | |

#Applied fisher exact test

**Table 2: Distribution of clinical variables in group A and B.**

| Parameters | Group A (N=27) | Group B (N=27) | p-value |
|---|---|---|---|
| Past History | | | |
| Present | 2(7.4) | 0 (0) | 0.491# |
| Not present | 25(92.6) | 27 (100) | |
| Family history | | | |
| Present | 3 (11.1) | 1 (3.7) | 0.610# |
| Not present | 24 (88.9) | 26 (96.3) | |
| Personal History | | | |
| Present | 7 (25.9) | 11 (40.7) | 0.248 |
| Not present | 20 (74.1) | 16 (59.3) | |

***Outcome measures***

*Hamilton Depression Rating Scale (HAM - D)*

Hamilton rating scale for depression scores of group A and B from baseline to 8 week is summarized in Table 3. Baseline score of group A was 18.78±1.78 and after 8 weeks was 7.67±1.66 while baseline scores of group B was 19.04±2.12 and after 8 week was 8.15±1.77. Difference in mean HAM D scores from baseline to 8 week in group A was 11.37±1.60 (p <0.001) and in group B was 11.48±1.97 (p <0.001) respectively.

*Hamilton Anxiety rating scale (HAM - A)*

Hamilton rating scale for Anxiety scores of group A and B from baseline to 8 weeks is summarized in Table 4. Baseline score of group A was 15.44±1.50 and after 8 weeks was 6.63±1.39. While baseline score of group B was 15.26±1.83 and after 8 week was 7.07±1.14. Difference in mean HAM A scores from baseline to 8 week in group A was 8.44±2.78 (p <0.001) and in group B was 8.63±1.98 (p <0.001) respectively.

*ASEX - Total adjusted score*

Thirteen patients enrolled in the study did not participate in sexual activity for last seven days, therefore they could not reply to questions of satisfaction and orgasm. Their score was adjusted to the total score. Arizona Sexual Experiences Scale scores of group A and B over 8 weeks are summarized in Table 5. Baseline scores of group A was 15.63±1.28 and at 8 week was 14.63±1.33. While baseline scores of group B was 15.52±1.37 and at 8 week was 16.41±1.12. From baseline to 8 week the difference in mean score in group A was +1.00±1.11 (p <0.001) and in group B it was -0.89±1.09 (p <0.001).

*ASEX - Desire score*

Sexual desire has been evaluated separately for this study, under the headings of sexual desire, sexual arousal, penile erection/ lubrication of vagina.

ASEX Desire scores of group A and B are summarized in Table 6. Baseline score of group A was 9.63±0.93 and at 8 week was 8.67±0.88. While baseline scores of group B were 9.59±0.93 and at 8 week were 10.07±0.92. From baseline to 8 weeks the difference in mean score in group A was +0.96±0.94 (p <0.001) and in group B was -0.48±0.75 (p=0.003).

*Udvalgfor Kliniske Undersogelser side effect rating scale (UKU)*

UKU side effect rating scale scores of group A and B over 8 week is summarized in Table 7. At 2 weeks scores of group A was 0.22±0.42 and at 8 week was 1.04±0.76 (p <0.001). At 2 weeks scores of group B were 0.37±0.49 and at 8 week were 1.89±0.85 (p <0.001).

**Table 3: HAM D scores (Mean±SD) of group A and B; comparison of HAM D scores between the groups at 0 wk, 8 wk and mean changes from 0-8 wks and within each group.**

| HAM D | Group A | Group B | t-value | p-value |
|---|---|---|---|---|
| At 0 week | 18.78±1.78 | 19.04±2.12 | -0.486 | 0.629 |
| At 8 weeks | 7.67±1.66 | 8.15±1.77 | -1.030 | 0.308 |
| Mean change 0-8 weeks | 11.37±1.60 | 11.48±1.97 | -0.228 | 0.821 |
| Within group t-value | 27.49 | 22.48 | | |
| Within group p-value | <0.001 | <0.001 | | |

**Table 4: HAM A scores (Mean±SD) of group A and B; comparison of HAM A scores between the groups at 0 wk, 8 wk and mean changes from 0-8 wks and within each group.**

| HAM A | Group A | Group B | t-value | p-value |
|---|---|---|---|---|
| At 0 week | 15.44±1.50 | 15.26±1.83 | 0.406 | 0.686 |
| At 8 weeks | 6.63±1.39 | 7.07±1.14 | -1.284 | 0.205 |
| Mean change 0-8 weeks | 8.44±2.78 | 8.63±1.98 | -0.282 | 0.779 |
| Within group t-value | 21.68 | 18.32 | | |
| Within group p-value | <0.001 | <0.001 | | |

**Table 5: ASEX total scores (Mean±SD) of group A and B; comparison of ASEX total scores between the groups at 0 wk, 8 wk and mean changes from 0-8 wks and within group.**

| ASEX T | Group A | Group B | t-value | p-value |
|---|---|---|---|---|
| At 0 week | 15.63±1.28 | 15.52±1.37 | 0.309 | 0.759 |
| At 8 weeks | 14.63±1.33 | 16.41±1.12 | -5.306 | <0.001 |
| Mean change 0-8 weeks | 1.00±1.11 | -0.89±1.09 | 6.32 | <0.001 |
| Within group t-value | 4.68 | -4.25 | | |
| Within group p-value | <0.001 | <0.001 | | |

**Table 6: ASEX desire scores (Mean±SD) of group A and B ; ASEX desire scores between the groups at 0 wk, 8 wk and mean changes from 0-8 wks and within each group.**

| ASEX D | Group A | Group B | t-value | p-value |
|---|---|---|---|---|
| At 0 week | 9.63±0.93 | 9.59±0.93 | 0.147 | 0.884 |
| At 8 weeks | 8.67±0.88 | 10.07±0.92 | -5.764 | <0.001 |
| Mean change 0-8 weeks | -0.96±0.94 | +0.48±0.75 | 6.233 | <0.001 |
| Within group t-value | 5.22 | 3.32 | | |
| Within group p-value | <0.001 | 0.003 | | |

**Table 7: UKU side effect scores (Mean±SD) of group A and B; UKU side effect scores between the groups at 2 wk, 8 wk and mean changes from 2-8 wks and within each group.**

| UKU | Group A | Group B | t-value | p-value |
|---|---|---|---|---|
| At 2 weeks | 0.22±0.42 | 0.37±0.49 | -1.185 | 0.241 |
| At 8 weeks | 1.04±0.76 | 1.89±0.85 | -3.892 | <0.001 |
| Mean change 2-8 week | 0.74±0.76 | 1.56±0.93 | -3.509 | 0.001 |
| Within group t-value | -5.39 | -8.09 | | |
| Within group p-value | <0.001 | <0.001 | | |

## DISCUSSION

This study was a comparison of vilazodone vis-a-vis sertraline, a well established SSRI antidepressant. The aim was to assess the clinical efficacy and sexual side-effects of vilazodone and sertraline over an 8 weeks treatment period.

A total of 102 patients were screened out of these 48 patients did not fulfil the selection criteria. The patients enrolled in the study were either new cases or the

previously treated cases who had not taken any medications in the past 6 months. The remaining 54 patients were allocated to either Group A or B.

The patients were enrolled in the order of arrival and were distributed in these blocks. Eventually both the groups had 27 patients each. Out of these patients five patients did not complete the second and the third follow up visit.

After selection and allotment of the patients, their details were recorded (identification data, demographic profile and clinical variables) on a semi structured proforma. Both the groups were compared using Chi-square test and Fisher value test on socio-demographic variables including age, sex, religion, marital status, family type, income, education and occupation.

***HAM-D***

HAM-D score at baseline (Mean±SD) in group A was 18.78±1.78 while that in group B was 19.04±2.12. On statistical comparison there was no significant difference between the two groups (p=0.629). After 8 weeks of treatment the mean HAM-D score in group A was 7.67±1.66 and in group B was 8.15±1.77. HAM-D scores of both the groups decreased from baseline after 8 weeks of treatment and this improvement was statistically significant. In group A (p<0.001 and in group B (p<0.001).

The decline in the mean scores from baseline to 8 week in group A and group B was 11.37±1.60 and 11.48±1.97 respectively. When this decline in mean score was compared statistically no significant difference (p=0.821) was obtained between the two groups. The decrease in the HAM-D score showed that both groups were treated effectively and there was a considerable improvement in the depressive symptoms meaning there by, that both medications are equally efficacious for treatment of depression.

In a study on clinical efficacy of vilazodone, the mean difference in HAM-D score was -10.5 from baseline to 8 week.[10] Another study on efficacy profile of vilazodone shows that the mean difference in HAM D score was -10.4 from baseline to 8 weeks and found it to be superior in treatment of depression (in this study -11.37 at 8 weeks).[11] An open label study of sertraline in adult patients showed that the mean difference in HAM-D score was -13.9 at 8 weeks, establishing the efficacy of sertraline in treatment of depression.[12]

Another study on effect of sertraline on depressive symptoms shows the mean difference in HAM D score was -9.97 at 6 weeks indicating the effectiveness of sertraline in recovery from depression and anxiety (in our study mean difference was -11.48 at 8 weeks).[13] These findings are in agreement to those observed in this study.

***HAM-A***

HAM-A score at baseline (Mean±SD) for group A was 15.44±1.50 and for group B was 15.26±1.83. When both the groups were compared statistically no significant difference was observed (p=0.686). After 8 weeks of treatment the mean score for group A was 6.63±1.39 while that of group B was 7.07±1.14. HAM-A scores of both the groups declined with 8 weeks of treatment.

The mean score decline from baseline to 8 weeks in group A and group B were 8.44±2.78 and 8.63±1.98 respectively. When this decline in mean score was compared statistically no significant difference (p=0.779) was found between the groups. The change in the HAM-A score implied that both these groups were effectively treated and there was considerable improvement in symptoms of anxiety.

In a placebo controlled trial on efficacy and safety of vilazodone, the mean difference in HAM A score was -7.1 from baseline to 8 weeks.[14] Another study on efficacy profile of vilazodone shows the mean difference in HAM A score was -6.5 as compared to placebo -5.2 after 8 week of treatment.[11] Yet in another study evaluating the efficacy of vilazodone the mean difference in HAM A score was -7.1 change from baseline in 8 week (in this study the mean change was -8.44±2.78).[15] In study, on efficacy of sertraline in a 12 week trial, HAM-A score changes from baseline to 4 and 12 weeks were -7.7 and -13.8 respectively ( in this study the mean score change was - 8.63±1.98 at 8 week).[16] Hence, results of this study are comparable to other studies and show a beneficial effect on anxiety symptoms with both medications.

***ASEX- Total Adjusted score***

ASEX-Total adjusted score includes sex drive, arousal, erection/lubrication, reaching orgasm and satisfactory orgasm. ASEX score at baseline with Mean±SD in group A was 15.63±1.28 and in group B was 15.52±1.37. When both the groups were compared statistically there was no significant difference (p=0.759). After 8 weeks of treatment the score in group A was 14.63±1.33 and in group B was 16.41±1.12. ASEX scores of group A have significant improvement while for group B the score having significant worsening from baseline to 8 weeks. When both the group were compared statistically, a significant difference (p<0.001) between both the groups was seen.

The mean scores changes from baseline to 8 week in group A and group B were 1.00±1.11 and -0.89±1.09 respectively. When mean score changes were compared statistically there was a significant difference (p<0.001) between the groups.

An open label randomized controlled study in depression showed that for the patient treated with vilazodone the ASEX score at 12 weeks was 11.73±3.55 (in this study

ASEX total score were 14.63±1.33 at 8 week).[17] In another study conducted on the effect of sertraline on sexual functioning in patients with major depressive disorder the ASEX total score at baseline was 19.13 and decline to 17.53 at 4 weeks and 17.83±6.64 at 8weeks, when compared statistically no significant difference is observed between baseline to 12 weeks or in mean change of ASEX score (in this study ASEX total score were 16.41±1.12 at 8 week).[18]

***ASEX - Desire***

ASEX - Desire questionnaire includes sex drive, arousal, erection/ lubrication. ASEX score at baseline (Mean±SD) in group A was 9.63±0.93 and in group B was 9.59±0.93. When both the groups were compared statistically there was no significant difference (p=0.884). After institution of treatment, the score at 8 weeks in group A was 8.67±0.88 and in group B was 10.07±0.92. ASEX score for group A showed significant improvement (p<0.001) at 8 weeks while that of group B showed a significant worsening (p=0.003) after 8 weeks. A statistically significant difference between both the groups was observed. The mean change in scores from baseline to 8 weeks in group A and group B were -0.96±0.94 and +0.48±0.75 respectively. When analyzed a significant statistical difference between both the groups was observed (p<0.001) after 8 weeks of treatment. In this study, calculated as end of treatment minus baseline, a negative value of mean score changes indicate improvement in function while positive value indicates worsening of function. It also indicated that improvement in sexual drive as well as improvement on arousal and penile erection/ lubrication of the vagina.

A study on treatment emergent sexual dysfunction related to antidepressants shows that sertraline has higher rate of sexual dysfunction such as sexual desire, sexual arousal.[19] The findings of this study are in agreement to the above mentioned study.

***UKU side effect rating scale***

In this study the UKU side effect rating scale was used for measuring the side effects of the antidepressant drugs (vilazodone and sertraline). The adverse effects related to anti-depressants may limit the compliance to treatment.[20] The side effects were divided into four categories including psychic side effects, neurologic side effects, autonomic side effects and others (e.g. weight changes, sexual desire, erectile dysfunction, ejaculatory dysfunction, headache).

UKU side effect scores of Group A and B are depicted in Table 7. The score at 2 weeks with Mean±SD in group A was 0.22±0.42 and in group B was 0.37±0.49. When both the groups were compared statistically there was no significant difference (p=0.241). After 8 weeks of treatment the scores in group A was 1.04±0.76 and in group B was 1.89±0.85. Hence a change in the UKU side effect rating scale was seen in both the groups. When both the groups were compared statistically a significant difference was observed (p<0.001). The change in mean scores from 2 to 8 weeks in group A and group B were 0.74±0.76 and 1.56±0.93 respectively. When change in mean score was compared statistically a significant difference was seen between the groups indicating lower incidence of side effects with vilazodone.

In the study on efficacy and safety of vilazodone assessed side effects of medication on clinical global impression severity rating scale the mean changes from baseline to 8 weeks was found to be significant.[15] In open label sertraline study assessed side effects on CSI-S the mean change from baseline to 8 weeks was significant.[12] This study provides evidence that vilazodone has similar efficacy as sertraline in terms of improving depression and anxiety. However, the occurrence of sexual side effects is lesser with vilazodone when compared to sertraline. Additionally, vilazodone has lesser side effects overall and is better tolerated.

Limitation of the study includes small sample size. Patients of specific age group (18-50 years) were enrolled in the study which limits the application of findings of this study to patients beyond this age range. The 8 week time period may be too short to assess the true long term side effects and effects on sexual functioning. This is important as antidepressants are usually continued for much longer periods.

## CONCLUSION

From the result and observation in the present study following conclusions may be drawn:

- Evaluation on HAM-D score revealed significant improvement of depressive symptoms at 8 weeks as compared to baseline in patients treated with Vliazodone 20- 40 mg H.S or Sertraline 50-100 mg H.S. This implies that both the drugs are efficacious in the treatment of depression.
- HAM-A score revealed significant improvement in symptoms of anxiety at 8 weeks as compared to baseline in patients treated with either Vilazodone or Sertraline.
- On evaluating ASEX-Total score as well as ASEX-Desire score a statistically significant change was observed at 8 weeks as compared to baseline. This improvement was significant for the patients who received Vilazodone. But the patients receiving Sertraline actually showed a significant worsening of score.
- UKU side effect rating scale revealed that Vilazodone has lesser side effects than Sertraline. The occurrence of sexual dysfunction and weight gain is a major side effects of SSRIs. Vilazodone seem to have lesser side effects than Sertraline and is better tolerated overall.

Thus, it can be concluded that Vilazodone and Setraline are equally efficacious in short term (8weeks) treatment of depression and associated anxiety. But when compared on the basis of side effect profile (occurrence of sexual dysfunction and other side-effects) Vilazodone is superior to Sertraline.

## ACKNOWLEDGEMENTS

Authors would like to thank Mr. Manoj Pandey (Consultant Statistician) for statistical analysis of the data and Torrent Pharmaceuticals for providing drugs at subsidized rate.

*Funding: No funding sources*
*Conflict of interest: None declared*
*Ethical approval: The study was approved by the Institutional Ethics Committee*

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**Cite this article as:** Arya N, Nischal A, Nischal A, Agarwal M. A comparative prospective open label randomized controlled 8 week study in patients of depression treated with vilazodone and sertraline. Int J Adv Med 2020;7:643-9.