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# A RANDOMIZED DOUBLE BLIND COMPARISON STUDY OF DULOXETINE VS VENLAFAXINE IN DEPRESSION WITH SOMATIC SYMPTOMS

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ABSTRACT

The purpose of this article was to compare the efficacy of duloxetine with venlafaxine, in patients diagnosed as depression with somatic symptoms. The diagnosis was based on ICD-10 criteria and a minimum score of 30 in depression and somatic symptoms scale [DSSS]. DSSS scores at baseline and 6 weeks after treatment were compared, and the results analysed and tabulated.

## INTRODUCTION

Depression is a common illness. there are many studies comparing duloxetine with venlafaxine in depression[1,2,3,4,5,6,7,8,9,10]. In indian setup psychological symptoms of depression may be masked by a dominant reporting of somatic symptoms, the so called masked depression. Studies comparing efficacy of antidepressants in this subgroup of depression is rare. Routine scales for assessing depression used in clinical studies do not give importance to somatic symptoms. They also do not treat the somatic aspect of depression as equal to that of the psychological symptoms.[11,12,13]

In clinical studies in depression ,Hamilton depression rating scale (HAMD) and Montgomery–Asberg depression rating scale (MADRS) are used commonly to evaluate depression. Though the 17-item HAMD has eight items related to somatic symptoms, six of the eight items are designed to look for vegetative symptoms, only two items code for somatic symptoms and account for just six points, or less than 12% of the total score. As somatic symptoms are reduced to just two items we can surely say these scales more or less ignore the somatic dimension.

Similarly in the MADRS scale, only two items look for vegetative symptoms (decreased appetite and insomnia) and none in the somatic dimension. So common scales used in assessing depression neglects somatic symptoms, and are deficient in giving importance to all dimensions of depression. This is much more appalling in a indian setup where psychological symptoms of depression may be masked by a dominant reporting of somatic symptoms.

In this scenario relying on these scales fully is not desirable. So in this study instead of conventional scales, depression and somatic symptoms scale [DSSS] is used [14,15,16]. As depression with somatic symptoms are more common in our country, and serotonin norepinephrine reuptake inhibitors [SNRI'S] are said to be more efficacious, in this sub group of depression, this study attempts to find which of the two main SNRI'S duloxetine or venlafaxine is more efficacious.

## MATERIALS AND METHODS

This study was conducted in a psychiatry out patient clinic between november 2016 and may 2017 . Patients who gave written informed consent were only included in this study.

## INCLUSION CRITERIA

1. Patients satisfying ICD-10 criteria for depressive episode with somatic symptoms
2. Both male and female patients in the age group of 25 to 50.
3 .Patients with a score of 30 and above in depression and somatic symptoms scale [DSSS].

## EXCLUSION CRITERIA

1. Patients with other comorbid illness
2. Patients who were pregnant
3. Patients who were breastfeeding
4. Patients with risk of suicide
5.patients with bipolar disorder

Patients satisfying ICD-10 criteria for depressive episode with somatic symptoms, and having a score of 30 or more in the depression and somatic symptoms scale were included.

Patients of both gender in the age group of 25 to 50 were included. The 112 patients were randomly divided into two groups of 56 patients each on alternate basis, first patient in duloxetine group second patient in venlafaxine group and likewise.

Dosage for patients in duloxetine group[D Group] was started at 40 mg and increased upto 120 mg as per need. Similarly in patients with venlafaxine group [V Group] dosage was started at 75 mg and gradually raised to 225mg.

Patients were given sedatives if needed.

After treatment for six weeks patients were again administered DSSS. Responders were defined as those who scored 22 or less in DSSS[17,18].

3 patients dropped out from duloxetine group and two from venlafaxine group due to adverse events.

## RESULTS AND DISCUSSION

After eliminating the dropouts there were 53 patients in D Group [duloxetine] and 54 in V Group [venlafaxine] .

**TABLE-1 DEMOGRAPHIC DETAILS**

| DEMOGRAPHIC DETAILS | D GROUP [DULOXETINE] | V GROUP [VENLAFAXINE] |
|---|---|---|
| TOTAL NO OF PATIENTS | 53 | 54 |
| MALE | 22 | 21 |
| FEMALE | 31 | 33 |
| AGE [MEAN±SD] | 35±7 | 34±6 |
| DSSS SCORE AT BASELINE | 47.887.52 | 45.875.02 |

So out of 53 patients in D Group 31 were female and 22 males. In the V Group male and females were 21 and 33 respectively. The mean age of patients in the D and V group were 35±7&34±6 respectively. The baseline DSSS score in the D and V group were 47.88±7.52 & 45.87±5.02.

**Table-2 DROP OUTS IN D GROUP**

| Duloxetine [D Group] | Drop outs due to side effects |
|---|---|
| Constipation | 1 |
| Impotence | 1 |
| Dry mouth | 1 |
| Total | 3 |

**Table -3 DROPOUTS IN V GROUP**

| Venlafaxine [V Group] | Drop outs due to side effects |
|---|---|
| Nervousness | 1 |
| Dizziness | 1 |
| Total | 2 |

The side effects causing dropouts in the D Group were, constipation, impotence and dry mouth. In the V Group dropouts were due to nervousness and dizziness.

**Table -4 RESPONDERS IN THE DULOXETINE [D GROUP]**

| Total no of patients | Responders | Percentage |
|---|---|---|
| 36 | 53 | 67.92 |

**Table-5 RESPONDERS IN THE VENLAFAXINE [ V GROUP]**

| Total no of patients | responders | percentage |
|---|---|---|
| 31 | 54 | 57.40 |

**Table- 6 PERCENTAGE OF RESPONDERS IN BOTH GROUPS**

| Percentage of responders | | P value |
|---|---|---|
| Duloxetine group | 67.92 | P < 0.001 |
| Venlafaxine group | 57.40 | |

The responders were defined as having a cutoff of 22or less in DSSS. [17,18]. There were 36 responders in the duloxetine group [67.92%] and 31 responders in the venlafaxine group [57.40%] and the difference was statistically significant [ p<0.001].

## CONCLUSION

The results of this study show that duloxetine is more effective than venlafaxine in depression with somatic symptoms. This study also outlines the fact that though somatic presentation of depression is common in india, the scales commonly used ignore this dimension . Rating scales have to be modified further 1.to pick up regional and cultural differences in presentation & 2 should cover all dimensions.

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