Original Article

Improvement in Quality of Life of Postmenopausal Women with Depression with commonly used Antidepressants (Escitalopram vs. Desvenlafaxine): A Randomized Controlled Trial in a Tertiary Care Teaching Hospital of North India

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ABSTRACT

Introduction: The postmenopausal symptoms affect the quality of life (QoL) of women. Depression and anxiety too have been associated with diminished QoL. It is known that antidepressants escitalopram and desvenlafaxine are effective in the treatment of depression and anxiety. However, to the best of our knowledge, their comparative effect on the QoL of postmenopausal women with depression and anxiety has not been studied in the Indian setup. **Materials and Methods:** The present study was a randomized, intention to treat, open-label trial undertaken in North India's a tertiary care teaching hospital. Postmenopausal women attending the psychiatry outpatient department and newly diagnosed with depression and anxiety were randomized in two groups to receive Tab. Escitalopram 10–20 mg and Tab. Desvenlafaxine 50–100 mg. Their QoL was assessed using the WHOQOL BREF scale at baseline, 3 weeks and 6 weeks. **Results:** Escitalopram was observed to be statistically better than desvenlafaxine in improving the overall QoL score of the WHOQOL-BREF scale. Individually, escitalopram significantly improved the scores of the physical health domain, psychological and environmental domains except for the social relationship domain. Desvenlafaxine significantly improved scores of all four domains. **Conclusion:** Escitalopram was observed to be significantly better than desvenlafaxine in improving the overall QoL scores. Both the drugs were well tolerated.

KEYWORDS: *Anxiety, depression, desvenlafaxine, escitalopram, postmenopausal women, quality of life*

INTRODUCTION

Postmenopausal symptoms affect the work, mood, concentration, energy levels, and social and sexual activity of the women. The quality of life (QoL), indicative of a person's perception and level of satisfaction with daily activities, of women suffering from severe symptoms is compromised if they do not take any treatment for the same.

Depression has also been associated with diminished functional impairment as well as diminished QoL.[1,2] It is known to hamper the QoL by having a negative effect on physical, mental, and social well-being.[3] Functional impairment can intensify psychological problems and may also persist even after symptom remission. Therefore, its restoration to predepression levels is as important as symptom amelioration.

Selective serotonin reuptake inhibitors and, most importantly, escitalopram are the well-established drugs of the first choice for depression and anxiety

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disorders.[4,5] Moreover, escitalopram was also observed to be effective in treating depression and anxiety in comparison to desvenlafaxine, in postmenopausal women, after a minimum of 6 weeks of treatment.[6]

As described earlier, depression has an adverse impact on the QoL and the functioning of postmenopausal women. Hence, in the present study, an attempt was made to study the effect of both drugs on the QoL of such women. To study the QoL, the WHOQOL-BREF scale was used. It is a short form of the original WHOQOL-100 scale. It allows domain-wise QoL assessment. WHOQOL-BREF has four basic domains, namely physical health, psychological, social relationships, and environment and two additional items of overall QoL and general health. The scores of each domain depict the patient's perception of QoL in each particular domain.[7]

Individually, both escitalopram and desvenlafaxine have been reported to be efficacious in improving the QoL of adult patients suffering from depression and anxiety.[2,8] However, to the best of our knowledge, we could not find any Indian study doing a head-to-head comparison of the effectiveness of these in improving the QoL in postmenopausal women with depression and anxiety. Therefore, a comparative evaluation of the efficacy of escitalopram versus desvenlafaxine on QoL in postmenopausal women with depression and anxiety was done.

Materials and Methods

The present study was a randomized, intention to treat, open-label trial undertaken in North India's tertiary care teaching hospital over a period of 6 months. It was initiated after prior approval of the Institutional Ethics Committee.

Written informed consent was obtained from patients. Patients were assessed for eligibility after applying inclusion and exclusion criteria. All principles of bioethics were followed.

Inclusion criteria

1. Postmenopausal women between 40 and 65 years of age with either natural or surgical menopause
2. Attending psychiatry outpatient department
3. Newly diagnosed with depression as per the Diagnostic and Statistical Manual-V criteria[9]
4. Total score of ≥ 18 on the Hamilton Depression Rating Scale[10]
5. Total score of ≥ 18 on the Hamilton Anxiety Rating Scale.[11]

Exclusion criteria

1. Women with uncontrolled comorbidities
2. Past history of major depression, bipolar disorder, and drug or alcohol abuse
3. Taking any prior psychopharmacological agents
4. On hormonal therapy
5. Diagnosed with endometrial or ovarian cancer, myocardial infarction, angina pectoris, cerebrovascular event, stroke, and acute illness
6. Having a history of intolerance or allergic reaction to the study drugs.

The included women were randomized to the two treatment arms in a ratio of 1:1 by the block permutation method. Women enrolled in Group 1 received flexible dose of tablet escitalopram 10–20 mg/day and those in Group 2 received tablet desvenlafaxine 50–100 mg/day.

The WHOQOL-BREF scale was used for the assessment of the QoL of these patients at the baseline visit, 3 weeks, and 6 weeks. It is a prevalidated and pretested scale with an internal consistency value of > 0.7. The scale showed good discriminant validity, content validity, and test–retest reliability.[7]

The values were recorded and compared at 0, 3, and 6 weeks. Paired and unpaired *t*-tests were used for intra and intergroup analysis at all follow-ups. $P < 0.05$ was considered to be statistically significant. All the patients were observed during the course of the study for adverse drug reactions.

Results

The demographic profile of the study population is as mentioned in Table 1. Baseline scores of various domains of the WHOQOL-BREF scale of the participants were comparable in both groups.

The mean overall QoL values in escitalopram and desvenlafaxine groups are as shown in Table 1. Treatment with escitalopram produced statistically significant improvement in comparison to placebo at the 6-week follow-up ($P = 0.008$) [Table 2].

Moreover, both the drugs showed significant improvement in the overall health of these patients after 3 and 6 weeks of treatment ($P < 0.001$). However, on intergroup comparisons, both the drugs were found to be comparable to each other at both the follow-ups. Both escitalopram and desvenlafaxine showed a comparable effect on the mean transformed scores (0–100) of the physical health domain on intergroup analysis [Table 3]. As far as the psychological improvement of these women was concerned, both the drugs showed statistically significant results ($P < 0.001$) at both 3- and 6-week follow-up. However, no drug was found to be better than the other on head-to-head comparison [Table 4]. The effects of the two drugs on the social relationship and environment domains are shown in Tables 5 and 6.

Table 1: Demographic characteristics of patients

Demographic variable	Mean±SD		Mean difference	*t*	*P*
	Escitalopram (*n*=20)	Desvenlafaxine (*n*=20)			
Age	51.60±7.76	48.95±6.81	2.650	1.148	0.258 (NS)
Age at menopause	45.88±5.05	44.45±5.50	1.425	0.853	0.399 (NS)
Duration since menopause	5.7±3.97	4.50±3.44	1.225	1.043	0.303 (NS)
	Frequency (%)		χ^2		*P*
Nature of menopause					
Natural	19 (95)	18 (90)	0.360		0.548 (NS)
Surgical	01 (05)	02 (10)			
Residence					
Urban	12 (60)	13 (65)	0.107		0.744 (NS)
Rural	08 (40)	07 (35)			

Comparison between the groups baseline scores with unpaired Student's *t*-test and Chi-square test: NS: Non-significant, SD: Standard deviation

Table 2: Comparative effect of escitalopram versus desvenlafaxine on mean "overall quality of life" score in WHOQOL-BREF scale

Time	Mean±SD Mean difference (% change)		*t*	*P*
	Escitalopram (*n*=20)	Desvenlafaxine (*n*=20)		
0 week	2.65±0.59	2.30±0.47	2.081	0.404 (NS)
3 weeks	3.35±0.67*** 0.70±0.47 (26.41)	3.05±0.61*** 0.75±0.44 (32.60)	1.485	0.146 (NS)
6 weeks	3.70±0.47*** 1.05±0.51 (39.62)	3.25±0.55*** 0.95±0.51 (41.30)	2.781	0.008††

SD- Standard Deviation; Paired't' test in comparison to respective baselines *** *P*<0.001; Comparison between the groups at Baseline, 3 weeks and 6 weeks with Unpaired Student t' test- †† *P*<0.01; NS = Non-Significant

Table 3: Comparative effect of escitalopram versus desvenlafaxine on mean transformed score (0-100) of "Physical Health (Domain 1)" in WHOQOL-BREF scale

Time	Mean±SD Mean difference (% change)		*t*	*P*
	Escitalopram (*n*=20)	Desvenlafaxine (*n*=20)		
0 week	41.20±07.11	43.10±7.31	−0.833	0.410 (NS)
3 weeks	49.15±10.45*** 07.95±5.67 (19.30)	49.15±7.91** 6.05±6.76 (14.04)	0.191	1.000 (NS)
6 weeks	54.25±08.47*** 13.05±8.01 (31.67)	50.75±8.87** 7.65±8.74 (17.75)	0.907	0.209 (NS)

SD- Standard Deviation; Paired't' test in comparison to respective baselines ** *P*<0.01, *** *P*<0.001; Comparison between the groups at Baseline, 3 weeks and 6 weeks with Unpaired Student t' test- NS = Non-Significant

The compliance of the patients was assessed by maintaining the pill count and by confirming the same from the family members in contact with the patients.

Gastritis was the most common adverse event observed in both groups. All the adverse events were mild in nature and did not require the withdrawal of treatment.

Discussion

There is a substantial prevalence of depression, of about 42.47% of perimenopausal and postmenopausal women in India.[12] Furthermore, in the United States, about 20% of women experience depression during their postmenopausal period.[13]

In the present study, escitalopram was found to be statistically better than desvenlafaxine in improving overall QoL after 6 weeks of treatment. This finding could be attributed to the fact that escitalopram was observed to be effective in treating depression in postmenopausal women after 6 weeks of treatment.[6] Thus, it can be suggested that there is a correlation between the amelioration of depression and the improvement in QoL of depressed postmenopausal women.

However, the results of the present study differ from those of Soares *et al.*, 2010, in which both the drugs were found to be comparable to each other in improving the QoL of postmenopausal women with depression and

Table 4: Comparative effect of escitalopram versus desvenlafaxine on mean transformed score (0-100) of "psychological domain (Domain 2)" in WHOQOL-BREF scale

Time	Mean±SD Mean difference (% change)		*t*	*P*
	Escitalopram (*n*=20)	Desvenlafaxine (*n*=20)		
0 week	41.95±14.34	40.75±8.95	0.317	0.753 (NS)
3 weeks	49.50±15.42***	47.07.05±5.81***	0.411	0.683 (NS)
	07.55±6.72 (18.00)	07.05±5.81 (17.30)		
6 weeks	56.10±12.31***	50.95±10.05***	1.450	0.155 (NS)
	14.15±8.79 (33.73)	10.20±8.50 (25.03)		

SD- Standard Deviation; Paired't' test in comparison to respective baselines *** *P*<0.001; Comparison between the groups at Baseline, 3 weeks and 6 weeks with Unpaired Student *t*' test- NS = Non-Significant

Table 5: Comparative effect of escitalopram versus desvenlafaxine on mean transformed score (0-100) of "social relationship (Domain 3)" in WHOQOL-BREF scale

Time	Mean±SD Mean difference (% change)		*t*	*P*
	Escitalopram (*n*=20)	Desvenlafaxine (*n*=20)		
0 week	47.20±19.07	43.45±13.35	0.720	0.476 (NS)
3 weeks	49.05±19.20#	45.95±14.09#	0.582	0.564 (NS)
	1.85±4.99 (3.92)	2.50±5.93 (5.75)		
6 weeks	50.30±18.67#	47.25±15.56*	0.561	0.578 (NS)
	3.10±6.89 (6.57)	3.80±6.66 (8.75)		

SD- Standard Deviation; Paired't' test in comparison to respective baselines *P<0.05, #Non Significant; Comparison between the groups at Baseline, 3 weeks and 6 weeks with Unpaired Student '*t*' test- NS = Non-Significant

Table 6: Comparative effect of escitalopram versus desvenlafaxine on mean transformed score (0-100) of "environment (Domain 4)" of in WHOQOL-BREF scale

Time	Mean±SD Mean difference (% change)		*t*	*P*
	Escitalopram (*n*=20)	Desvenlafaxine (*n*=20)		
0 week	55.75±13.29	54.80±13.84	0.221	0.826 (NS)
3 weeks	58.25±14.67*	56.65±11.79*	0.383	0.704 (NS)
	2.50±4.75 (4.48)	1.85±3.50 (3.38)		
6 weeks	62.30±13.53***	58.55±12.29**	0.917	0.365 (NS)
	6.55±6.60 (11.75)	3.75±4.27 (6.84)		

SD- Standard Deviation; Paired't' test in comparison to respective baselines *P<0.05, **P<0.01, ***P<001; Comparison between the groups at Baseline, 3 weeks and 6 weeks with Unpaired Student *t*' test- NS = Non-Significant

anxiety even after 6 months of therapy.[14] The difference in results could be due to different demographic profiles of the patient population, larger sample size, different study design and treatment regimen, longer duration of the study, and differences in the doses used.

Furthermore, in the present study, both escitalopram and desvenlafaxine were individually found to be effective in improving the QoL of these women. Various authors in the past have substantiated the respective efficacy of escitalopram in improving the QoL of patients in comparison to placebo or some other drugs.[15-18] Similarly, in a study by Wang *et al*., 2018, escitalopram significantly improved the QoL as measured by the Quality of life Enjoyment and Satisfaction Questionnaire-Short Form (Q-LES-Q-SF) score after 2 weeks of treatment in postmenopausal women with depression and comorbid anxiety.[2] Furthermore, Endicott *et al*., 2014, observed that there was a statistically significant improvement from baseline in 10 of 16 Quality of Life Enjoyment and Satisfaction Questionnaire item scores in adult outpatients with major depressive disorder after 12 weeks of treatment with desvenlafaxine, as compared to placebo with $P \leq 0.044$.[19]

In this study, escitalopram was individually effective in improving scores in psychological, physical, and environmental domains at both 3 weeks and 6 weeks. No improvement was seen in the social domain score even after 6 weeks of treatment. Similar findings were reported in a study by LaCroix *et al*., 2012, done in healthy postmenopausal women.[20]

However, there is a paucity of studies doing a domain-wise head-to-head comparison of both the drugs like our study.

Conclusion

Thus, it was observed that escitalopram was more effective than desvenlafaxine in improving the overall QoL of postmenopausal women suffering from depression and anxiety after at least 6 weeks of treatment. Moreover, both the drugs appeared to be equally safe and well tolerated. Although the results of this study are promising, it is required to generate more evidence base by conducting large-scale randomized controlled trials before the findings can be put to clinical use.

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Conflicts of interest

There are no conflicts of interest.

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