



# Escitalopram versus Hormone Therapy (Norethindrone Acetate and Ethinyl Estradiol): Impact on Depression, Sleep, Vasomotor Symptoms, and Quality of Life in Peri and Postmenopausal Women



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## ABSTRACT

- The menopausal transition appears to be a period of heightened vulnerability to mood disturbance, leading to a significant adverse impact on quality of life and social functioning.
- Menopausal women with depressive disorders (n=38) were randomized to receive an 8-week open treatment with escitalopram (flexible dose 10-20mg) or Hormone Therapy (HT) to alleviate depression, menopause-related symptoms, and to improve quality of life (QOL).
- At week 8, escitalopram was more efficacious than HT in treating depressive disorders (75% versus 25%, respectively). Both treatment groups showed significant improvement of vasomotor symptoms, sleep and QOL.
- After an 8-week extension phase, 60% (6/10) of women who had not responded satisfactorily to HT achieved remission of depression with concomitant use of escitalopram.

## BACKGROUND

- Antidepressants have shown to be efficacious for the treatment of menopause-related depressive disorders. Preliminary data also suggest that antidepressants alleviate vasomotor symptoms.
- The efficacy of Hormone Therapy (HT) for the treatment of vasomotor symptoms is well established. On the other hand, the use of HT for menopause-related mood and anxiety symptoms has shown mixed results. Moreover, the safety of long-term use of HT has been questioned.

## METHODS

### Subjects

- 38 women were enrolled in the study (15 perimenopausal, 23 postmenopausal, 40-60 years old).
- Perimenopausal status, irregular cycles and amenorrhea for <12 months; postmenopausal, amenorrhea ≥12 months.
- Diagnosis of depressive disorders (M.I.N.I. interview).
- No contraindications to HT.

### Analysis

- Intent-to-treat, LOCF; N=32, 16 on HT, 16 on escitalopram.
- Nonparametric procedures.
- α=.05 for all analyses.

## METHODS (Cont.)

MEASURES	DEFINITION
Remission of Depression	MADRS < 10 at week 8; sub-scores for depressed mood < 4
Remission of Menopause-related Symptoms	≥ 50% decrease in GCS scores (excluding psychological sub-scores) from baseline to week 8.
Remission of Hot Flashes	GCS vasomotor sub-scores ≤1 at week 8 HFRDIS total score <10 at week 8 ≥ 50% decrease in Hot Flash composite score
Improvement in Sleep	Pittsburgh Sleep Quality Index sub-scores
Improvement in Quality of Life	Changes in MENQOL from baseline to week 8
Overall Remission	Remission of Depression and Menopause-related Symptoms

## RESULTS

### Patient characteristics

- At baseline, both treatment groups were similar with respect to menopausal status, severity of depression, or severity of menopause-related symptoms (p>0.05 Pearson  $\chi^2$  tests)

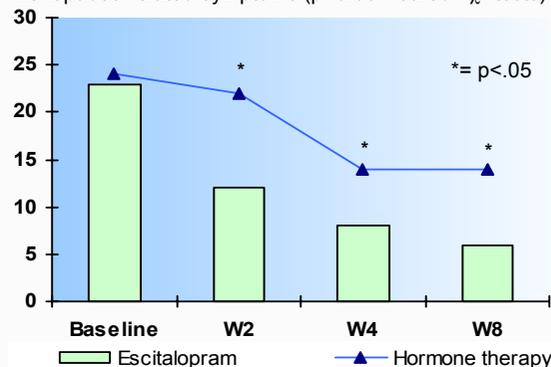


Figure – Changes in depressive symptoms (MADRS- Montgomery-Asberg Depression Rating Scale, median scores), from baseline to week 8, in subjects treated with escitalopram (n=16) or hormone therapy (n=16).

## RESULTS (Cont.)

### 1. Treatment Outcome (8 weeks)

- Full remission of depression** was observed in 75%(12/16) of subjects treated with escitalopram, compared to 25%(4/16) treated with HT; p=0.01, Fisher  $\chi^2$  tests .
- Remission of menopause-related symptoms** was noted in 7/16 (43.8%) women treated with escitalopram, and 6/16 (37.5%) treated with HT; p=0.50, Fisher  $\chi^2$  tests
- Remission of Hot Flashes** – there were no significant differences (p>0.05,  $\chi^2$  tests) between escitalopram and HT, based on the following instruments:  
-GCS vasomotor sub-scores: 66.7% versus 60%  
-HFRDIS scores: 56.3% versus 62.5%  
-Hot Flash Composite scores: 53.3% versus 73.3%
- Overall remission** was observed in 56.3% (9/16) of women treated with escitalopram, and in 12.5% (2/16) of women treated with HT; p=0.02 (Fisher  $\chi^2$  test).

- Improvement in Sleep** was observed in both treatment groups (p>0.05, Fisher  $\chi^2$  tests), assessed by Pittsburgh Sleep Quality Index sub-scores for sleep efficiency and sleep disturbance.

- Improvement in Quality of Life** was significant, and observed in both treatment groups, as assessed by changes in MENQOL scores

### 2. Treatment Outcome (8-week extension phase)

Ten of the 12 non-responders to HT alone received an 8-week combination of escitalopram and HT

- Remission of depression** occurred in 60% of subjects
- Remission of hot flashes** occurred in 70% of subjects

## CONCLUSIONS

- Escitalopram was more efficacious than HT for the treatment of depressive disorders in menopausal women.
- Escitalopram may constitute an option to treat symptomatic menopausal women who are unable or unwilling to receive treatment with HT.