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Randomized Clinical Trial

Effects of hormone replacement therapy on mood and sleep quality in menopausal women

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Abstract

BACKGROUND

Hormone replacement therapy is an effective treatment strategy for the management of symptoms in naturally menopausal women. However, some patients report experiencing adverse effects.

AIM

To analyze the effects of hormone replacement therapy in menopausal female patients.

METHODS

A total of 152 menopausal female patients admitted to the Gynecology Department of the Ganzhou Maternal and Child Health Hospital between January 2021 and December 2023 were divided into the observation group (n = 76, conventional treatment + hormone replacement therapy) and the control group (n = 76, conventional treatment only) *via* random casting. The improvement observed in the following items were compared between the groups: Kupperman menopausal index (KMI), emotional state [The Positive and Negative Affect Scale (PANAS)], sleep quality [Self-Rating Scale of Sleep (SRSS)], treatment effectiveness, and treatment safety.

RESULTS

The modified KMI and SRSS scores of the observation group were lower than those of the control group after three rounds of treatment. The improvement in the PANAS score observed in the observation group was greater than that observed in the control group ($P < 0.05$). The total treatment effectivity rate in the observation group was higher than that in the control group (86.84% *vs* 96.05%, $\chi^2 = 4.121$, $P = 0.042$). The incidence rate of adverse reactions in the two groups was comparable (6.58% *vs* 9.21%, $\chi^2 = 0.361$, $P = 0.547$).

CONCLUSION
Hormone replacement therapy effectively improved the clinical symptoms, actively channeled negative emotions, and improved the quality of sleep in menopausal patients, indicating its effectiveness and safety.

Key Words: Hormone replacement therapy; Menopause; Women; Mood states; Sleep quality; Sex hormones

Core Tip: Menopausal females can benefit from hormone replacement therapy; however, this treatment may increase the risk of venous thrombosis, cardiovascular disease, and breast cancer.

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INTRODUCTION

Menopause, a normal part of the aging process in women, is characterized by changes in the hormone levels, biochemical environment, and psychological state of the patients. Menopause heralds the gradual decline of ovarian function resulting in the complete disappearance of ovarian function. If not diagnosed and treated in a timely manner, menopause affects the physiological and psychological health of the patients and interferes with their daily life and work[1]. Conventional treatment strategies encompassing psychological, diet, exercise, and other interventions have exhibited beneficial effects in relieving physical and mental stress. However, achieving the desired effect *via* the application of these strategies alone is difficult in clinical practice[2]. Hormone replacement therapy is a therapeutic method that involves the administration of synthetic hormones to treat the symptoms caused by insufficient hormone secretion. This method can effectively relieve the discomfort associated with menopausal symptoms[3]. However, previous studies have shown[4] that the overall effect of hormone replacement therapy cannot meet the expectations of women who have been menopausal for > 10 years or those aged > 60 years; moreover, it also significantly increases the absolute risk of coronary heart disease, venous thromboembolism, and dementia. Clinical reports on the use of hormone replacement therapy in menopausal women are controversial. Therefore, 152 menopausal women were randomly included in the present study and analyzed to further elucidate the benefits and drawbacks of hormone replacement therapy.

MATERIALS AND METHODS

General information

This study was approved by the Medical Ethics Committee of the Ganzhou Maternal and Child Health Hospital. The patients and their family members were provided with a detailed explanation regarding the objective of the study. Informed consent was obtained prior to commencing the study. In accordance with the random throw method, 152 menopausal patients admitted to the Department of Gynecology of the Ganzhou Maternal and Child Health Hospital between January 2021 and December 2023 were divided into the control (n = 76) and observation (n = 76) groups. The characteristics of the two groups were compared to detect statistically significant differences (P > 0.05; Table 1).

The inclusion criteria were as follows: Patients with available laboratory, imaging, and other comprehensive assessment results who met the disease determination criteria[5]; patients with natural menopause persisting for > 6 months; patients who had not received hormone drug therapy 3 months before enrollment; and voluntary participation, with the provision of written informed consent.

The exclusion criteria were as follows: History of allergy, history of malignant disease or serious organic injury, history of mental disorder or mental illness, and declined/withdrawn participation.

Methodology

The patients in the control group received conventional treatment, *i.e.* psychological adjustment. The patients were guided to relax their bodies and minds *via* rhythmic deep breathing and encouraged to express their true inner thoughts and concerns. The concerns of the patients were considered and appropriate verbal encouragement and action support were provided. The importance and necessity of maintaining a good state of mind were explained to the patients *via* positive and negative case education. Patients presenting with serious psychological symptoms were offered professional psychological counseling. In addition to these measures, the patients were encouraged to cultivate hobbies and interests and actively participate in social activities.

Table 1 Comparison of baseline information between the two groups

Baseline information		Control, *n* = 76	Observation, *n* = 76	t/χ^2	*P* value
Age in years		55.02 ± 4.05	54.59 ± 4.26	0.638	0.525
Disease duration in years		3.86 ± 1.14	4.12 ± 1.30	1.311	0.192
Body mass index in kg/m^2		24.87 ± 0.95	25.04 ± 0.92	0.121	0.264
Educational level	High school and below	49 (64.47)	45 (59.21)	0.446	0.504
	Above high school	27 (35.53)	31 (40.79)		

Data are mean ± SD or *n* (%).

Dietary adjustment: The patients were instructed to consume < 300 mg of cholesterol, < 6 g of salt, ≤ 50 g of sugar, ≤ 15 g of alcohol, and 1000 mg of calcium per day. In addition, they were also instructed to drink 1500-1700 mL of water per day and consume fresh fruits and vegetables; foods high in calcium, such as fish, meat, eggs, and milk; and high-fiber or whole-grain foods.

Exercise management: The patients were encouraged to perform regular physical activities, such as 150 minutes of moderate-intensity aerobic exercise per week. In addition, the patients were recommended to perform activities, such as cycling, swimming, square dancing, walking, jogging, or yoga, according to their strength, while paying attention to the gradual progress. Muscle training exercises were added according to the needs of the patient.

Medication guidance: Medications, such as antidepressants and melatonin receptor agonists, were administered according to the needs of the patient. Strict compliance with the use of medications was ensured.

In addition to the interventions: The patients in the observation group also received hormone replacement therapy. Estradiol valerate tablets (0.5 mg; Beijing Union Pharmaceutical Factory; State Drug Permit H20000031) were administered orally at a dose of 1 mg once a day for 14 days. Multiple modes of administration were available; however, oral ingestion of estradiol valerate tablets is predominantly utilized for the supplementation of estrogen deficiency associated with either natural or surgical menopause. Consequently, the present study employed the oral route for drug administration. In addition to administering estradiol valerate tablets on the 15th day, hydroxyprogesterone acetate tablets (0.25 g; Beijing Slippery Pharmaceuticals Ltd; State Drug Permit H11021562) were administered orally at a dose of 8 mg once a day for 14 days. The treatment cycle comprised three courses (28 days). Detections were conducted within 3 days post-therapy conclusion.

Observation indicators

Improvement in symptoms (before treatment *vs* after three courses of treatment). The modified Kupperman menopausal index (KMI) score[6] was used to evaluate 13 items: Hot flashes and sweating (0-12 points), sensory abnormalities (0-6 points), insomnia (0-6 points), moodiness (0-6 points), depression (0-3 points), vertigo (0-3 points), osteoarthralgia/muscle pain (0-3 points), headache (0-3 points), fatigue (0-3 points), palpitations (0-3 points), sexuality (0-3 points), crawling sensation of the skin (0-3 points), urological sensations (0-3 points), and skin pain (0-3 points). The total score ranged from 0 to 63 points, with a higher score indicating more severe symptoms.

Emotional state (before treatment *vs* after three courses of treatment): The Positive and Negative Affect Scale (PANAS) score[7] is a scale comprising two dimensions (positive and negative emotions). Each dimension consists of 10 adjectives; each adjective was scored on a 5-point Likert scale (1-5 points). The emotional state of the patient was positively correlated with the score obtained.

Quality of sleep (before treatment *vs* after three courses of treatment): The Self-Rating Scale of Sleep (SRSS) score[8], which contains the following 10 items, was used to assess the quality of sleep. Insufficient duration of sleep, poor quality of sleep, insufficient sleep/wakefulness, duration of sleep, difficulty falling asleep, disturbed sleep, early rising, dreaming/nightmares/night terrors, medication use, attitude toward sleep, and physiological and psychological reactions to insomnia. Minimum and maximum values of 1 point and 5 points, respectively, were assigned to each item. A higher score indicated a poorer quality of sleep.

Treatment effectiveness: Resolution of symptoms after three courses of treatment and a reduction in the modified KMI score of at least 80% was defined as cure. Significant improvement in the clinical symptoms after three courses of treatment, and a reduction in the modified KMI score of 50%-80% was defined as a significant effect. Reduction in the clinical symptoms after three courses of treatment, and a reduction in the modified KMI score of 20%-50% was defined as effective treatment. No reduction in the clinical symptoms after three courses of treatment, and a reduction in the modified KMI score of < 20% was defined as ineffective treatment[9]. The overall treatment effectiveness rate was calculated as the sum of the cure, significant, and effective rates.

Treatment safety: The incidence of adverse reactions (*e.g.*, nausea and vomiting, breast swelling and pain, and irregular vaginal bleeding) in the two groups was recorded.

Statistical analysis

All statistical analyses were performed using SPSS27.0 software. The normality of data distribution was determined. Normally distributed data were compared between the groups using independent samples *t*-test. Intra-group differences were evaluated using the paired samples *t*-test. Counts are presented as the percentage rate (%) and were evaluated using the χ^2 test. $P < 0.05$ was considered statistically significant.

RESULTS

Comparison of symptom improvement between the two groups

The modified KMI scores of the two groups were well-balanced before treatment, with no statistically significant differences ($P > 0.05$). The modified KMI scores of the two groups decreased after three courses of treatment. The magnitude of the decrease in the observation group was greater, and the difference was statistically significant ($P < 0.05$). Table 2 presents further details.

Comparison between the emotional states of the two groups

The scores obtained for each dimension of the PANAS score by the two groups were well-balanced before treatment, and the difference was not statistically significant ($P > 0.05$). The PANAS scores of the two groups improved after three courses of treatment. The magnitude of the improvement in the observation group was greater, and the difference was statistically significant ($P < 0.05$). Table 3 presents further details.

Comparison between the sleep quality of the two groups

The SRSS scores of the two groups were well-balanced before treatment, with no statistically significant differences ($P > 0.05$). The SRSS scores of the two groups decreased after three courses of treatment. The magnitude of the decrease in the observation group was greater, and the difference was statistically significant ($P < 0.05$). Table 4 presents further details.

Comparison between treatment effectiveness observed in the two groups

Comparison of the total treatment effectiveness rates of the two groups revealed that the rate of the observation group was higher, and the difference was statistically significant (86.84% *vs* 96.05%, $\chi^2 = 4.121$, $P = 0.042$). Table 5 presents further details.

Comparison between the safety of treatment observed in the two groups

The incidence of adverse reactions did not significantly differ between the groups (6.58% *vs* 9.21%, $\chi^2 = 0.361$, $P = 0.547$). Table 6 provides further details.

DISCUSSION

Epidemiological data[10] shows that the prevalence of menopause and menopausal symptoms in the reproductive, menopausal transition, and postmenopausal stages is 9.3%, 23.9%, and 21.5%, respectively. Menopause is a physiological process that women must undergo. The occurrence of menopause is mainly related to the gradual depletion of follicles in the ovaries caused by a significant decline in female hormones. Poor lifestyle habits also promote the occurrence of menopause to a certain extent[11]. Conventional treatment can regulate the psychological state of patients and encourage them to consciously adopt behaviors that are beneficial. However, its effect on improving their condition is relatively limited. Hormone replacement therapy is an effective treatment strategy for the management of symptoms in naturally menopausal women. Thus, its use for the management of menopause has been recognized and endorsed. However, some patients report experiencing breast distension and pain, vaginal bleeding, and other discomforts, which are associated with certain adverse effects to an extent[12,13].

The dysfunction of the hypothalamic-pituitary-ovarian axis owing to the decrease in estrogen levels results in an imbalance in neurotransmitter, cytokine, and hormone levels, thereby inducing menopause. The findings of the present study demonstrated that the reduction in the KMI score of the observation group was greater than that in the control group after three courses of treatment ($P < 0.05$). This may be attributed to the following reasons: Estradiol valerate is an estrogenic drug administered as a part of hormone replacement therapy. It can increase the estrogen levels and improve menopausal symptoms, regulate the reproductive and endocrine systems to further maintain ovarian function, and delay the progression or avoid further deterioration of the disease. Medroxyprogesterone acetate is a progestational hormone drug that can inhibit the secretion of gonadotropin-releasing hormone in the hypothalamus *via* reverse feedback. Furthermore, it can reduce the luteinization of the anterior pituitary gland. Methylprogesterone acetate is a progestin that can inhibit the secretion of hypothalamic gonadotropin-releasing hormone *via* reverse feedback, reduce the secretion of luteinizing hormone in the anterior pituitary gland, and regulate the secretion of estradiol in the ovary to influence the physiological activities of the reproductive system. These actions have a positive effect on the alleviation of menopausal

Table 2 Comparison of symptom improvement between the two groups

Content	Time	Control, *n* = 76	Observation, *n* = 76	*t* value	*P* value
Hot flashes and sweating	Pre-treatment	8.35 ± 1.27	8.20 ± 1.32	0.714	0.476
	Post-treatment	4.24 ± 1.18[a]	3.78 ± 1.09[a]	2.496	0.014
Abnormal sensations	Pre-treatment	3.52 ± 0.47	3.43 ± 0.50	1.143	0.255
	Post-treatment	2.05 ± 0.36[a]	1.93 ± 0.24[a]	2.418	0.017
Insomnia	Pre-treatment	3.23 ± 0.61	3.35 ± 0.58	1.243	0.216
	Post-treatment	2.14 ± 0.43[a]	1.98 ± 0.32[a]	2.602	0.010
Agitation	Pre-treatment	3.12 ± 0.45	3.03 ± 0.37	1.347	0.180
	Post-treatment	1.69 ± 0.28[a]	1.60 ± 0.15[a]	2.470	0.015
Depression	Pre-treatment	1.87 ± 0.36	1.90 ± 0.42	0.473	0.637
	Post-treatment	1.15 ± 0.19[a]	1.09 ± 0.10[a]	2.436	0.016
Vertigo	Pre-treatment	1.41 ± 0.29	1.38 ± 0.27	0.660	0.510
	Post-treatment	1.01 ± 0.17[a]	0.95 ± 0.08[a]	2.784	0.006
Bone and joint pain/muscle pain	Pre-treatment	1.93 ± 0.35	1.87 ± 0.40	0.984	0.327
	Post-treatment	1.31 ± 0.22[a]	1.24 ± 0.09[a]	2.567	0.011
Headaches	Pre-treatment	1.61 ± 0.53	1.58 ± 0.60	0.327	0.744
	Post-treatment	1.02 ± 0.34[a]	0.90 ± 0.23[a]	2.549	0.012
Fatigue	Pre-treatment	1.73 ± 0.42	1.68 ± 0.37	0.779	0.437
	Post-treatment	1.19 ± 0.30[a]	1.08 ± 0.24[a]	2.496	0.014
Palpitations	Pre-treatment	1.49 ± 0.38	1.52 ± 0.43	0.456	0.649
	Post-treatment	0.83 ± 0.25[a]	0.74 ± 0.19[a]	2.499	0.014
Crawling sensation of the skin	Pre-treatment	1.17 ± 0.26	1.22 ± 0.30	1.098	0.274
	Post-treatment	0.73 ± 0.18[a]	0.67 ± 0.10[a]	2.540	0.012
Sexuality	Pre-treatment	3.47 ± 0.58	3.38 ± 0.61	0.932	0.353
	Post-treatment	2.03 ± 0.35[a]	1.90 ± 0.24[a]	2.671	0.008
Urinary tract infection	Pre-treatment	3.02 ± 0.49	3.06 ± 0.54	0.478	0.633
	Post-treatment	1.88 ± 0.36[a]	1.75 ± 0.27[a]	2.518	0.013

[a]*P* < 0.05 compared with this group before treatment.
Data are mean ± SD.

Table 3 Comparison between emotional states observed in the two groups

Group	*n*	Positive emotions		Negative emotions	
		Pre-treatment	Post-treatment	Pre-treatment	Post-treatment
Control	76	20.45 ± 5.23	32.79 ± 5.46[a]	34.58 ± 5.69	22.81 ± 5.37[a]
Observation	76	20.59 ± 5.37	35.08 ± 5.54[a]	34.23 ± 5.72	20.64 ± 5.15[a]
t value		0.163	2.567	0.378	2.543
P value		0.871	0.011	0.706	0.012

[a]*P* < 0.05 compared with this group before treatment.
Data are mean ± SD.

Table 4 Comparison between sleep quality of the two groups

Group	*n*	Insufficient sleep		Poor quality of sleep		Insufficient sleep or wakefulness		Sleep duration		Difficulty in sleeping	
		Pre-treatment	Post-treatment	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment
Control	76	3.47 ± 0.81	2.21 ± 0.53[a]	2.91 ± 0.67	2.08 ± 0.35[a]	3.08 ± 0.72	2.39 ± 0.48[a]	2.84 ± 0.52	2.02 ± 0.31[a]	2.69 ± 0.40	1.77 ± 0.24[a]
Observation	76	3.52 ± 0.79	2.02 ± 0.38[a]	2.88 ± 0.70	1.96 ± 0.23[a]	3.11 ± 0.69	2.22 ± 0.31[a]	2.90 ± 0.57	1.91 ± 0.24[a]	2.73 ± 0.46	1.69 ± 0.15[a]
t value		0.385	2.540	0.270	2.498	0.262	2.594	0.678	2.446	0.572	2.464
P value		0.701	0.012	0.788	0.014	0.793	0.010	0.499	0.016	0.568	0.015

[a]$P < 0.05$ compared to this group before treatment.
Data are mean ± SD.

Table 5 Comparison of treatment effectiveness between the two groups

Group	*n*	Curable	Conspicuous effect	Efficiently	Null	Overall effectiveness of treatment
Control	76	20 (26.32)	29 (38.16)	17 (22.37)	10 (13.16)	66 (86.84)
Observation	76	24 (31.58)	30 (39.47)	19 (25.00)	3 (3.95)	73 (96.05)
χ^2						4.121
P value						0.042

Data are *n* (%).

Table 6 Comparison between treatment safety in the two groups

Group	*n*	Nausea and vomiting	Breast swelling and pain	Irregular vaginal bleeding	Incidence of adverse reactions
Control	76	2 (2.63)	1 (1.32)	2 (2.63)	5 (6.58)
Observation	76	2 (2.63)	3 (3.95)	2 (2.63)	7 (9.21)
χ^2					0.361
P value					0.547

Data are *n* (%).

symptoms. The findings of the present study are consistent with the those of the study Armeni *et al*[12].

Abnormal secretion of sex hormones, often accompanied by increased psychogenic anxiety, emotional instability, and irritability, is observed in menopausal women. In addition to symptoms of depressed mood, somatic symptoms, such as menopausal somatic discomfort, and autonomic dysfunction have also been reported[14]. Previous studies have shown [15] that women experiencing menopause are prone to developing sleep disorders (16%-47% and 35%-60% in perimenopausal and postmenopausal women, respectively) and that they mainly present with symptoms of insomnia with or without anxiety or low depression and mood disorders. The findings of the present study demonstrated that the SRSS scores were generally lower in the observation group and that the PANAS scores were significantly higher in the observation group after three courses of treatment ($P < 0.05$). This may be attributed to hormone replacement therapy gradually restoring the sex hormone secretion level, which can help in maintaining a stable mood and prevent and control the occurrence of tossing, turning, and sleeplessness owing to emotional excitement and anxiety. Thus, hormone replacement therapy can effectively alleviate negative mood and sleep disorders.

The data presented in Tables 5 and 6 show that the total treatment effectiveness rate and incidence of adverse reactions in the observation group were 96.05% and 9.21%, respectively. This may be attributed to hormone replacement therapy compensating for the insufficient secretion of sex hormones in menopausal women and targeting the discomfort caused by the symptoms related to menopause. Nevertheless, commencing hormone replacement therapy can result in breast swelling and pain, vaginal bleeding, and other adverse reactions. Therefore, clinicians must be careful with the use of these drugs and take measures to avoid excessive accumulation of estrogen or progesterone in the body and increased incidence of tumors and cardiocerebral and cerebral vascular diseases. The findings of the study conducted by Vigneswaran *et al*[15] confirm this view.

CONCLUSION

The application of hormone replacement therapy has a definite effect. It can effectively alleviate the symptoms of menopause and facilitate return to normal life. Thus, it is worthwhile to promote its use. However, hormone replacement therapy is a "double-edged sword". If the harm outweighs the benefits associated with the application of the treatment, it can cause serious adverse consequences and further endanger the patient's daily life and health. Thus, the application of hormone replacement therapy should be commenced after thorough individual risk stratification and assessment. Clinicians should select a suitable treatment plan after judging whether the patient is suitable for treatment by fully weighing the advantages and disadvantages and avoid adverse outcomes.

FOOTNOTES

Author contributions: Liu Q and Huang Z designed the research study; Liu Q, Huang Z, and Xu P performed the primary literature review and data extraction, analyzed the data, and wrote the manuscript; Liu Q and Huang Z revised the manuscript for important intellectual content; All authors have read and approved the final version.

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