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Original Research Article

Effect of hormone replacement therapy on biochemical parameters in post-menopausal women

Jayaprada Thigula*

Department of Obstetrics and Gynecology, Maheshwara Medical College and Hospital, Isnapur, Patancheru, Hyderabad, Telangana, India

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*Correspondence:

Dr. Jayaprada Thigula,

E-mail: drjaya.pujari@gmail.com

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ABSTRACT

Background: In females, menopause is a loss of natural events that marks the end of the reproductive years. Menopause its associated complications can be managed by hormone replacement therapy (HRT). This study hypothesized to evaluate the effect of hormone replacement therapy on clinico biochemical levels in postmenopausal women.

Methods: A total one hundred postmenopausal females were considered. Based on medication administered patients were divided in to five groups i.e. Premarin group, Ovral-L group, Evalon group, Transdermal E2 Gel group and Control group with oral calcium placebo therapy. A complete Haemogram, ECG, Urine examination, lipid profile were investigated.

Results: Most common clinical symptoms is vasomotor/psychological (45% in all groups) related followed by urogenital/psychological symptoms (22% in all groups). The mean lipid lipoproteins before therapy, after 2 months and 6 months follow up showed significant change in all the groups.

Conclusions: HRT can be a safe method to manage urogenital complication and vasomotor symptoms in postmenopausal women. It has a notable impact on the lipid profile and lipoproteins which helps to reduce the chances to get associated health complications.

Keywords: Menopause, Hormone replacement therapy (HRT), Lipoproteins, Lipid profile

INTRODUCTION

Menopause is a natural and inevitable phenomenon and serves as an objective sign of reproduction senescence and produces various symptoms which leads to adverse effects in women's life. The average age of menopause in India varies from 45-50 years. But approximately 8% of women undergo menopause before the age of 40 years or it may be delayed to 53 years.¹

Hormone replacement therapy (HRT) al so known as menopausal hormone therapy (MHT), is a medication containing the hormones that a woman's body stops

producing after menopause. HRT is helpful to prevent the occurrence of osteoporosis, cardio vascular diseases, vasomotor, bowel cancers and urogenital complications.

In menopause, there is increased risk of coronary heart disease due to adverse changes in serum lipid and lipoprotein levels. Evidences suggesting that, decreased serum oestrogen level had an unfavourable effect on serum lipoprotein concentration.²⁻⁵

Serum levels of total cholesterol, low-density lipoprotein (LDL) and lipoprotein were reduced, while serum levels of high-density lipoprotein (HDL) and triglyceride were

increased after oral administration of estrogen.⁶ On the contrary, serum levels of total cholesterol, LDL and lipoprotein were reduced, while serum levels of HDL and triglyceride remained the same after transdermal administration of estrogen.⁷⁻⁹

With the above facts, the present study designed to evaluate the effect of hormone replacement therapy on clinico biochemical levels in postmenopausal women.

METHODS

The present study was carried out in Department of Obstetrics and Gynaecology, Maheshwara Medical College and Hospital, Patancheru, Hyderabad. The patients attending outpatient department between age group > 45-70 years during August 2016 to May 2017 were recruited for the present study. A total 100 postmenopausal females with amenorrhoea more than 6 months, panhysterectomy at least one month back with one or other climacteric symptoms, were selected for study.

Inclusion criteria

Complaints like insomnia, dry vagina, burning micturition, vaginal discharge, palpitation, hot flushes, oligomenorrhoea and dyspareunia.

Exclusion criteria

Patients who had major complication in post-operative period, genital neoplasm, carcinoma breast, vaginal

bleeding, diabetes, hypertension and cardiovascular diseases were excluded from this study.

Data collection

Detailed obstetrical history of the patient was collected i.e. age of menopause, menstrual history, family history and drug history was collected. Clinical examination for cardiovascular diseases, psychological complications, breast examination and pervaginal examination was done. A complete Haemogram for Hb, ESR, blood sugar, ECG, Urine examination, lipid profile were investigated.

Based on medication, patients were divided in to five groups i.e. group I received oral Tab premarin 0-625 mg/day in repetitive (one week off after 3 weeks), group II received Tab evalon 1 mg/day in repetitive (one week off after 3 weeks), group III received tab oval-L levonorgestrel 0.15mg with ethinylestradiol 0.03mg, group IV administered with transdermal oestrogen, group V or control group with oral calcium tablet 1000 mg/day.

RESULTS

Majority of the patients belongs to 45-50 years in all the groups. No patients were between age group 61-65 and 66-70 years. No patients under E2 gel and Oval-L group between 56-60 years (Table 1). In this study, majority cases were multipara and grand multipara but no cases presented with nullipara and primipara. According to the duration of menopause from onset, more number of patients were between 0-5 years of onset in all the groups followed by 6-10 years (Figure 1).

Table 1: Distribution of cases according to age.

S.N.	Age (in years)	Premarin		Evalon		E2 Gel		Oval – L		Control	
		No	%	No	%	No	%	No	%	No	%
1	46-50	14	70	12	60	14	70	15	75	12	60
2	51-55	4	20	6	30	6	30	5	25	7	35
3	56-60	1	5	2	10	-	-	-	-	1	5
4	61-65	1	5	-	-	-	-	-	-	-	-
5	66-70	-	-	-	-	-	-	-	-	-	-
Total		20	100	20	100	20	100	20	100	20	100

In the view of clinical manifestations in menopausal women, majority of patients showing vasomotor/psychological symptoms in all groups.

The second commonest symptom is urogenital/psychological symptoms in all the groups cumulatively (Table 2).

The mean lipid lipoproteins before therapy, after 2 months and 6 months of therapy showed significant

change in all the groups (Table 3). The above table showing relief of symptoms as per patient information, after 2 months of HRT in premarin group 50% cases moderate relief and 50% showed significant change.

In Ovalar-L group, 85% showed Moderate relief and 15% showed significant relief after 2 months of therapy. In evalon group, 45% cases showed moderate relief and 55% showed significant relief after 2 months of therapy. In E2 Gel group, equal distribution of cases showed mild and significant relief after 2 months of therapy.

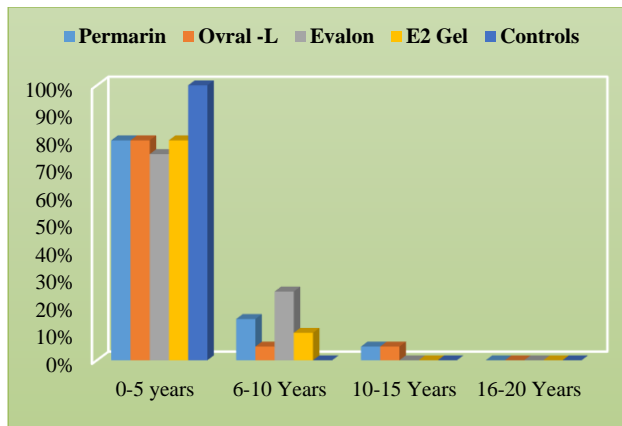


Figure 1: Distribution of cases as per duration of Menopause from onset.

In control group under placebo therapy, 70% showed no response, 25% showed moderate and 5% showed significant change after 2 months of hormone replacement therapy (Table 4). After 6 Months of hormone replacement therapy, in premarin group 90% showed complete abolition of symptoms and 10% showed significant change. In ovral-L group, 65% showed complete abolition of symptoms and 35% showed significant change. In evalon group, 80% showed complete abolition of symptoms and 20% showed significant change. In E2 gel group, 100 showed complete abolition of symptoms and in controls under placebo therapy, 55% with no relief, 40% with moderate relief and 5% with significant relief in symptoms (Table 4).

Table 2: Clinical symptoms observed in cases.

Clinical Symptoms	Group I (Premarin)		Group II (Ovral – L)		Group III (Evalon)		Group IV (E2 Gel)		Group V (Controls)	
	No	%	No	%	No	%	No	%	No	%
Vasomotor/ Urogenital	4	20	1	5	1	5	3	15	7	35
Vasomotor/ Psychological	10	50	9	45	10	50	7	35	9	45
Vasomotor/ Urogenital/ Psychological	3	15	5	25	5	25	4	20	-	-
Urogenital / Psychological	3	15	5	25	4	20	6	30	4	20
Total	20	100	20	100	20	100	20	100	20	100

Table 3: Mean values of lipid profile in all the drug groups.

Drug	Duration of therapy	STC (mg/dl) (mean±SD)	STG (mg/dl) (mean±SD)	HDL(mg/dl) (mean±SD)	LDL (mg/dl) (mean±SD)
Premarin	Before therapy	221.4±23.65	126.9±23.76	42.6±5.45	147.1±17.88
	After 2 months	215.2±21.79	128.3±21.05	43.3±5.29	139.6±17.64
	After 6 months	206.6±20.98	131.1 ±26.62	44.3±5.18	131.5±15.52
Ovaral- L	Before therapy	212.4±21.02	122.7 ±20.08	41.2±3.70	140.5±15.32
	After 2 months	204.1±18.63	125.1 ±18.82	43.7±4.15	133.7±13.24
	After 6 months	197.7±15.54	129.7 ±16.67	45.8±5.38	124.5±11.43
Evalon	Before therapy	209.5±15.35	127.4 ±15.54	38.8±4.91	139.9±14.69
	After 2 months	205.5±13.52	129.2 ±14.02	39.5±4.20	131.4±12.16
	After 6 months	199.8±10.91	132.8 ±12.75	41.9±3.73	129.1±10.44
E2 Gel	Before therapy	211.4±21.10	127.3 ±22.89	39.8±5.63	144.1±12.65
	After 2 months	208.2±19.53	128.6 ±21.09	41.7±5.48	137.0±10.44
	After 6 months	204.5±16.08	131.9 ±19.37	43.5±6.01	132.5±9.98
Controls (Placebo)	Before therapy	205.4±19.83	123.0 ±29.98	43.9±4.76	130.6±9.98
	After 2 months	203.1±15.60	123.5 ±27.54	42.3±5.23	132.8±8.56
	After 6 months	202.9±12.45	123.8 ±26.12	40.8±4.78	134.2±9.06

DISCUSSION

Hormone replacement therapy (HRT) is a vital medical importance in the care of ageing women with menopause,

especially in work committed. In menopausal women, HRT showing a protective measure against Osteoporosis, urogenital atrophy, atherosclerosis, skin and brain tissue degeneration and other age related complications.¹⁰⁻¹⁶

Table 4: Distribution of cases as per relief of symptoms after 2 and 6 months of HRT.

Group	Time period (in months)	No change		Moderate		Significant change		Complete abolition		Grand total	
		No	%	No	%	No	%	No	%	No	%
Premarin	2	-	-	10	50	10	50	0	0	20	100
	6	-	-	0	0	2	10	18	90	20	100
Ovral- L	2	-	-	17	85	3	15	0	0	20	100
	6	-	-	0	0	7	35	13	65	20	100
Evalon	2	-	-	9	45	11	55	0	0	20	100
	6	-	-	0	0	4	20	16	80	20	100
E2 Gel	2	-	-	10	50	10	50	0	0	20	100
	6	-	-	0	0	0	0	20	100	20	100
Controls (Placebo)	2	14	70	5	25	1	5	0	0	20	100
	6	11	55	8	40	1	5	0	0	20	100

Multiple therapeutic choices were exist for use, oral therapy is the most preferential and affordable hormone treatment.

The present study included one hundred postmenopausal patients to evaluate comparative efficacy of different type of HRT. All patients were examined thoroughly for clinical manifestations, vaginal smear pattern, serum lipoproteins, liver function test. Re-evaluation of all things was done 2 months and 6 months after therapy. In present study, minimum 60% cases were between age group 45-50 years in all groups (Premarin 70%, Evalon 60%, E2 Gel 70%, Ovral-L 75% and Controls 60%). None of the patients were between 61-70 years. In India, the average age group of women being prescribed for hormone replacement therapy is 45-55 years which is lesser than WHO and HERS norms.¹⁷ Majority patients were multipara and grand multipara in this study

In the present study, serum lipid lipoprotein levels were estimated in postmenopausal women undergoing HRT. In premarin group, the mean basal level of serum cholesterol (STC), triglyceride (STG), High Density lipoprotein (HDL) and Low Density lipoprotein (LDL) were 221.4 mg/dl, 126.9 mg/dl, 42.6 mg/dl and 147.1 mg/dl respectively. The mean STC and LDL were significantly decreased after 2 months and 6 months of therapy and Mean STG and HDL were significantly increased with advancement of therapy in premarin group. In Ovral-L, evalon and E2 Gel groups, the mean basal levels of STC and LDL were significantly increased and STG and HDL were significantly decreased when compared to before and after therapy (Table 3). In control group or under placebo therapy, the mean values of STC and LDL were gradually decreased and LDL was significantly increased but no change was observed in the levels of STG. Studies suggests that serum lipid levels are significantly higher in post-menopausal women and effect of hormone replacement therapy on serum lipid levels are also significant.¹⁸⁻²⁰

In the present study, clinical manifestations in menopausal women, majority of patients showing vasomotor/psychological symptoms in all groups. The second commonest symptom is urogenital/psychological symptoms in all the groups cumulatively (Table 2).

CONCLUSION

With the advancement of treatment modalities, a wide range of hormone related drugs for a better life of menopausal women were available and each has got its own merits and demerits. This study concluding that the hormone replacement therapy can be safe method to manage urogenital complication and vasomotor symptoms in postmenopausal women. The HRT have notable impact on the levels of Serum total cholesterol, Serum triglycerides, HDL and LDL which may helpful to minimise the chances to acquire psychological and cardiovascular symptoms.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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