



PATTERNS OF HORMONE REPLACEMENT THERAPY USE AND ITS EFFECT ON MENOPAUSAL SYMPTOMS AND METABOLIC PROFILE IN POSTMENOPAUSAL WOMEN: A PROSPECTIVE CLINICAL STUDY

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ABSTRACT

Introduction: Menopause is a natural biological transition in a woman's life associated with declining estrogen levels, leading to a wide range of vasomotor, psychological, and metabolic disturbances. Hormone Replacement Therapy (HRT) is widely used for the management of menopausal symptoms, but its usage patterns and metabolic effects vary among populations.

Aims and Objectives: To assess the pattern of Hormone Replacement Therapy (HRT) use and its effect on menopausal symptoms and metabolic profile in postmenopausal women, including evaluation of symptom relief and changes in metabolic parameters among HRT users compared to non-users.

Materials and Methods: This prospective hospital-based observational study was conducted in the Department of Obstetrics and Gynaecology, Deben Mahato Govt Medical College (MS) over 18 months. A total of 120 postmenopausal women attending the outpatient department were included and divided into HRT users and non-users. Clinical data, menopausal symptoms, and metabolic parameters were assessed and compared between groups.

Results: Age distribution was similar in both groups ($p = 0.68$). Estrogen + progesterone was the most common HRT (63.3%). HRT users had significantly lower vasomotor scores ($p < 0.001$) and showed improved lipid profile, glycemic status, BMI, and blood pressure compared to non-users ($p = 0.04$ to <0.001).

Conclusion: HRT is effective in improving menopausal symptoms and may have a favorable effect on lipid profile in postmenopausal women. However, careful patient selection and monitoring are essential due to potential metabolic variations and adverse effects. Individualized therapy based on symptom severity and risk profile is recommended.

Keywords: Menopause, Hormone Replacement Therapy, Postmenopausal Women, Metabolic Profile, Vasomotor Symptoms.

INTRODUCTION

Menopause is a natural biological transition in a woman's life, defined as the permanent cessation of menstruation resulting from the loss of ovarian follicular activity.

It is diagnosed retrospectively after 12 months of amenorrhea and typically occurs between 45 and 55 years of age. The menopausal transition is associated with a wide spectrum of clinical manifestations due to declining estrogen levels, which affect multiple organ systems and significantly influence quality of life [1]. These changes include vasomotor symptoms such as hot flashes and night sweats, psychological disturbances including mood swings, anxiety, and depression, as well as urogenital symptoms like vaginal dryness and dyspareunia [2]. Beyond symptomatic manifestations, menopause is also associated with significant metabolic alterations. Estrogen deficiency contributes to unfavorable changes in lipid metabolism, increased central adiposity, insulin resistance, and endothelial



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dysfunction, thereby increasing the risk of cardiovascular disease (CVD) and metabolic syndrome in postmenopausal women [3]. These metabolic changes make menopause not only a reproductive milestone but also an important cardiovascular and metabolic risk transition period. Hormone Replacement Therapy (HRT), which involves the administration of estrogen alone or in combination with progestin, has been widely used as the most effective treatment for moderate to severe menopausal symptoms, particularly vasomotor instability [4]. HRT significantly improves quality of life by reducing hot flashes, improving sleep disturbances, and enhancing overall well-being. However, its role in metabolic modulation and long-term cardiovascular outcomes remains a subject of ongoing debate [5]. Several observational and clinical studies have suggested that HRT may have beneficial effects on lipid profiles, including increased high-density lipoprotein (HDL) cholesterol and reduced low-density lipoprotein (LDL) cholesterol levels [6]. Estrogen therapy has also been shown to improve insulin sensitivity and may reduce the risk of type 2 diabetes in some populations. However, these metabolic benefits must be balanced against potential risks, including thromboembolic events, breast cancer, and stroke, particularly in long-term or late initiation of therapy [7]. The pattern of HRT use varies widely across populations depending on age, symptom severity, awareness, socioeconomic status, and physician prescribing practices. Following the results of the Women's Health Initiative (WHI) study, there was a global decline in HRT use due to concerns about associated risks [8]. However, more recent evidence suggests that when appropriately prescribed in early postmenopausal women, HRT may provide more benefits than risks, leading to renewed interest in its selective use [9]. Despite extensive research, there remains a gap in understanding real-world patterns of HRT use and its combined effects on menopausal symptoms and metabolic parameters, particularly in developing countries where lifestyle factors and healthcare access differ significantly from Western populations. Moreover, individualized response to HRT in terms of symptom relief and metabolic outcomes is not fully established, necessitating further prospective evaluation. Given this background, the present study aims to evaluate the patterns of HRT use and its effects on menopausal symptoms and metabolic profile in postmenopausal women in a clinical setting. Understanding these associations will help in optimizing therapeutic strategies, improving patient selection, and minimizing risks associated with HRT use [10]. To assess the pattern of Hormone Replacement Therapy (HRT) use and its effect on menopausal symptoms

and metabolic profile in postmenopausal women, including evaluation of symptom relief and changes in metabolic parameters among HRT users compared to non-users.

MATERIALS AND METHODS

Study design: Prospective, hospital-based observational clinical study.

Study setting: The study was conducted in Deben Mahato Govt Medical College, Dept of Obstetrics and Gynaecology MS.

Period of study: 18 Months.

Study population: Postmenopausal women attending the outpatient department of a tertiary care hospital.

Sample size: 120

Inclusion criteria:

- Postmenopausal women (≥ 12 months of amenorrhea)
- Age group typically 45–65 years
- Willing to participate in the study and give informed consent
- Women attending outpatient/inpatient services of the tertiary care hospital
- Both HRT users and non-users included for comparison

Exclusion criteria:

- Women with surgical menopause (bilateral oophorectomy or hysterectomy-induced menopause)
- History of hormone-dependent malignancies (e.g., breast or endometrial cancer)
- Severe systemic illness (advanced liver, renal, or cardiac disease)
- Current use of medications affecting lipid or glucose metabolism (e.g., statins, steroids)
- Uncontrolled endocrine disorders (e.g., thyroid disease, diabetes mellitus with complications)
- Non-compliant patients or those unwilling to complete follow-up

Statistical analysis: For statistical analysis data were entered into a Microsoft Excel spreadsheet and then analyzed by SPSS (version 27.0; SPSS Inc., Chicago, IL, USA) and Graph Pad Prism version 5. Data had been summarized as mean and standard deviation for numerical variables and count and percentages for categorical variables. Z-test (Standard Normal Deviate) was used to test the significant difference of proportions. Once a t value is determined, a p-value can be found using a table of values from Student's t-distribution. If the calculated p-value is below the threshold chosen for statistical significance (usually the 0.10, the 0.05, or 0.01 level), then the null hypothesis is rejected in favor of the alternative hypothesis. P-value ≤ 0.05 was considered for statistically significant.

RESULT

Table 1: Age-wise Distribution of Study Participants (N = 120)

Age Group (years)	HRT Users (n=60)	Non-Users (n=60)	Total	p-value
45–50	18 (30.0%)	15 (25.0%)	33	0.68 (NS)
51–55	22 (36.7%)	20 (33.3%)	42	
56–60	12 (20.0%)	15 (25.0%)	27	
>60	8 (13.3%)	10 (16.7%)	18	
Total	60	60	120	

Table 2: Type of HRT Used Among Users (n = 60)

Type of HRT	Number (n)	Percentage (%)
Estrogen alone	28	23.30%
Estrogen + Progesterone	76	63.30%
Tibolone	16	13.40%
Total	120	100%

Table 3: Effect on Vasomotor Symptoms

Symptoms Severity	HRT Users (n=60)	Non-Users (n=60)	p-value
Mild	36 (60.0%)	14 (23.3%)	<0.001 (S)
Moderate	18 (30.0%)	28 (46.7%)	
Severe	6 (10.0%)	18 (30.0%)	
Mean symptom score	4.2 ± 1.1	7.8 ± 1.4	

Table 4: Lipid Profile Comparison

Parameter	HRT Users (Mean ± SD)	Non-Users (Mean ± SD)	p-value
Total Cholesterol (mg/dL)	186 ± 24	204 ± 28	0.002
LDL (mg/dL)	110 ± 18	132 ± 22	<0.001
HDL (mg/dL)	52 ± 8	44 ± 7	<0.001
Triglycerides (mg/dL)	148 ± 26	162 ± 30	0.01

Table 5: Glycemic Status Comparison

Parameter	HRT Users (n=60)	Non-Users (n=60)	p-value
Fasting Blood Glucose (mg/dL)	102 ± 12	110 ± 15	0.003
HbA1c (%)	5.9 ± 0.6	6.3 ± 0.7	0.01

Table 6: Body Mass Index (BMI) and Blood Pressure

Parameter	HRT Users (Mean ± SD)	Non-Users (Mean ± SD)	p-value
BMI (kg/m ²)	26.4 ± 3.2	27.8 ± 3.6	0.04
Systolic BP (mmHg)	124 ± 12	132 ± 14	0.01
Diastolic BP (mmHg)	78 ± 8	82 ± 9	0.03

Figure 1: Age-wise Distribution of Study Participants

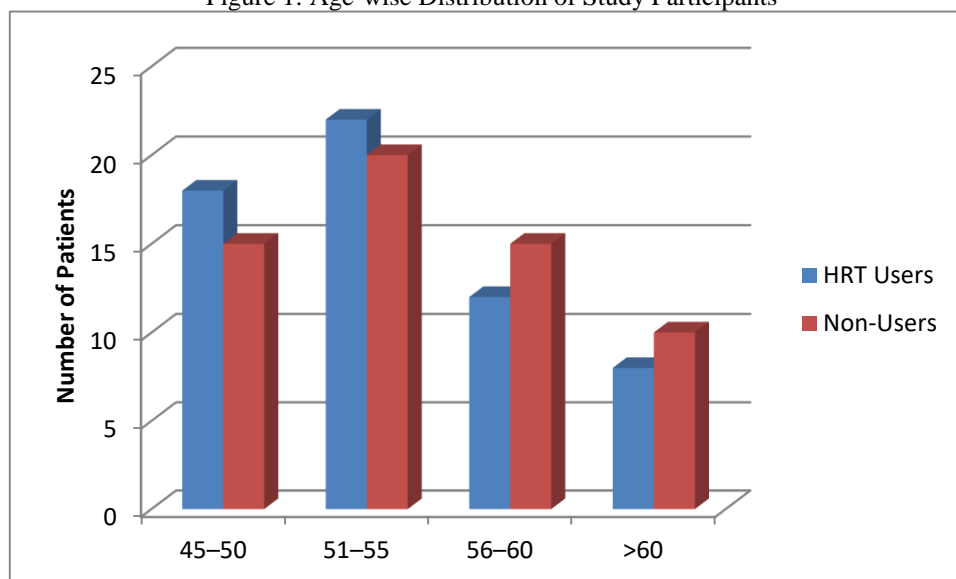
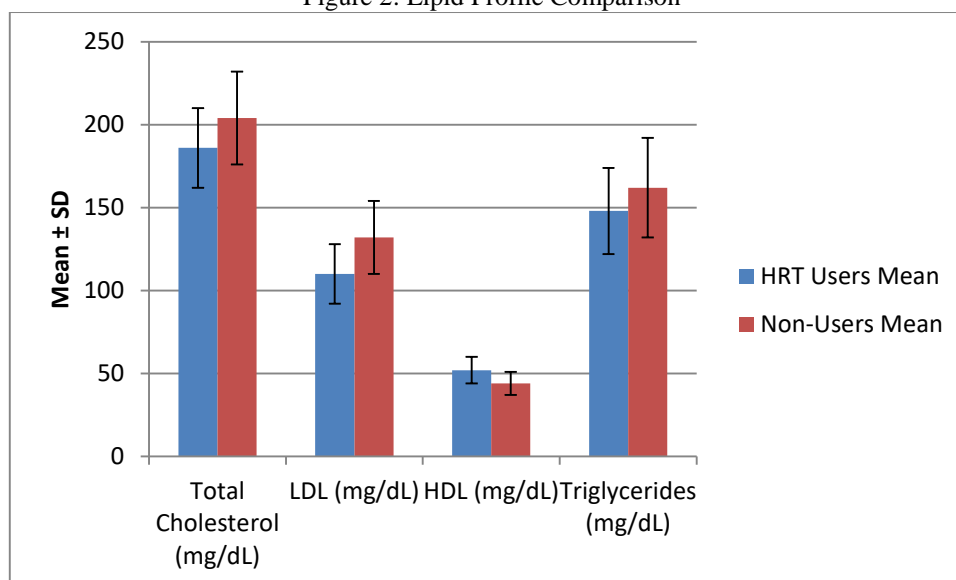


Figure 2: Lipid Profile Comparison



Age-wise Distribution of Study Participants (N = 120)

Result:

The majority of patients belonged to the 51–55 years age group (35.0%, n = 42), followed by 45–50 years (27.5%, n = 33), 56–60 years (22.5%, n = 27), and >60 years (15.0%, n = 18). The age distribution between HRT users and non-users was not statistically significant (p = 0.68).

Interpretation:

The study population showed a comparable age distribution between HRT users and non-users, indicating good group matching and eliminating age as a confounding factor in outcome analysis.

Type of HRT Used Among Users (n = 120)

Result:

Among HRT users, the most commonly used regimen was Estrogen + Progesterone (63.3%, n = 76), followed by Estrogen alone (23.3%, n = 28) and Tibolone (13.4%, n = 16).

Interpretation:

Combination HRT was the most frequently prescribed regimen, likely due to its protective effect against endometrial hyperplasia, making it the preferred clinical choice in postmenopausal women.

Effect on Vasomotor Symptoms

Result:

Mild vasomotor symptoms were observed more in HRT users (60.0%, n = 36) compared to non-users (23.3%, n = 14). Severe symptoms were more common in non-users (30.0%, n = 18) than HRT users (10.0%, n = 6). The mean symptom score was

significantly lower in HRT users (4.2 ± 1.1) compared to non-users (7.8 ± 1.4), with $p < 0.001$.

Interpretation:

HRT use was significantly associated with reduction in vasomotor symptom severity, indicating its effectiveness in improving menopausal symptom burden and quality of life.

Lipid Profile Comparison

Result:

HRT users had significantly lower total cholesterol (186 ± 24 mg/dL) compared to non-users (204 ± 28 mg/dL). LDL cholesterol was also lower in HRT users (110 ± 18 vs 132 ± 22 mg/dL), while HDL cholesterol was higher (52 ± 8 vs 44 ± 7 mg/dL). Triglycerides were lower in HRT users (148 ± 26 vs 162 ± 30 mg/dL). All differences were statistically significant ($p = 0.002$ to <0.001).

Interpretation:

HRT demonstrated a favorable effect on lipid metabolism, improving cardiovascular risk profile by increasing HDL and reducing LDL and total cholesterol levels.

Glycemic Status Comparison

Result:

Fasting blood glucose was lower in HRT users (102 ± 12 mg/dL) compared to non-users (110 ± 15 mg/dL). HbA1c was also lower in HRT users ($5.9 \pm 0.6\%$ vs $6.3 \pm 0.7\%$), with statistically significant differences ($p = 0.003$ and $p = 0.01$, respectively).

Interpretation:

HRT use was associated with improved glycemic control, suggesting a possible beneficial effect on insulin sensitivity in postmenopausal women.

BMI and Blood Pressure

Result:

BMI was lower in HRT users (26.4 ± 3.2 kg/m²) compared to non-users (27.8 ± 3.6 kg/m²). Similarly, systolic blood pressure (124 ± 12 vs 132 ± 14 mmHg) and diastolic blood pressure (78 ± 8 vs 82 ± 9 mmHg) were lower in HRT users. All differences were statistically significant ($p = 0.04$, $p = 0.01$, $p = 0.03$ respectively).

Interpretation:

HRT use was associated with modest but significant improvement in BMI and blood pressure, indicating a potential beneficial effect on metabolic and cardiovascular parameters.

DISCUSSION

Menopause is a physiological process characterized by a decline in ovarian estrogen production, leading to a variety of vasomotor, psychological, and metabolic disturbances that significantly affect quality of life in postmenopausal women. Hormone Replacement Therapy (HRT) remains the most effective treatment for alleviating menopausal symptoms, particularly vasomotor instability such as hot flashes and night sweats [11]. In the present

prospective clinical study, we evaluated the patterns of HRT use and its effects on menopausal symptoms and metabolic profile in 120 postmenopausal women. In our study, the majority of women were in the 51–55 years age group, with no statistically significant difference between HRT users and non-users ($p = 0.68$). This indicates proper comparability between groups, reducing age-related confounding effects. Similar findings were reported by Santoro et al., who observed that menopausal symptoms are most prominent in early postmenopausal years [12]. Regarding patterns of HRT use, estrogen-progesterone combination therapy was the most commonly prescribed regimen in our study (63.3%). This is consistent with global recommendations, where combined HRT is preferred in women with an intact uterus to prevent endometrial hyperplasia and carcinoma [13]. Tibolone and estrogen-only therapies were used less frequently, reflecting cautious prescribing patterns following long-term safety concerns highlighted by large trials. A significant reduction in vasomotor symptoms was observed among HRT users compared to non-users ($p < 0.001$). The mean symptom score was markedly lower in HRT users, demonstrating the high efficacy of hormone therapy in symptom control. These findings are consistent with the Women's Health Initiative (WHI) trial and subsequent studies, which confirmed that estrogen-based therapy significantly reduces hot flashes and improves sleep quality [14]. In terms of metabolic profile, our study demonstrated a favorable lipid pattern among HRT users, with lower total cholesterol and LDL and higher HDL levels ($p \leq 0.002$). These results are supported by Rossouw et al., who reported that estrogen therapy exerts a beneficial effect on lipid metabolism by increasing hepatic LDL receptor activity and enhancing HDL synthesis [15]. However, despite these favorable biochemical changes, large randomized trials have shown that lipid improvement does not always translate into reduced cardiovascular events, emphasizing the complexity of hormone-related metabolic effects [16]. Glycemic parameters in our study also showed significant improvement among HRT users, with lower fasting blood glucose and HbA1c levels. This suggests improved insulin sensitivity, which has been previously described in observational studies. Canonico et al. reported that estrogen therapy may improve glucose homeostasis and reduce the risk of type 2 diabetes when initiated early in menopause [17]. We also observed a modest reduction in BMI and blood pressure among HRT users. Although the differences were statistically significant, the magnitude was small. This finding aligns with evidence suggesting that HRT may help in preventing central fat accumulation and improving vascular endothelial function, thereby contributing

to slight reductions in blood pressure [18]. However, these benefits must be weighed against potential risks such as thromboembolism and breast cancer, particularly with prolonged use. Overall, our findings indicate that HRT not only provides effective relief from menopausal symptoms but also has favorable effects on metabolic parameters, particularly lipid and glycemic profiles. Nevertheless, the decision to initiate HRT should always be individualized, taking into account patient age, symptom severity, and risk factors. Recent guidelines from the North American Menopause Society emphasize the importance of personalized therapy and the lowest effective dose for the shortest duration [19]. The strengths of our study include its prospective design and simultaneous evaluation of both symptomatic and metabolic outcomes. However, limitations include a relatively short follow-up period and lack of long-term cardiovascular outcome assessment. Future large-scale randomized studies are required to better define the long-term risk–benefit profile of HRT in diverse populations [20].

CONCLUSION

This prospective clinical study demonstrates that Hormone Replacement Therapy (HRT) is significantly associated with improvement in menopausal symptoms, particularly vasomotor symptoms, and also shows favorable effects on metabolic parameters including lipid profile, glycemic status, BMI, and blood pressure in postmenopausal women. Estrogen–progesterone combination therapy was the most commonly used regimen. Overall, HRT appears to be an effective therapeutic option for symptom relief and metabolic benefit, but its use should be individualized based on patient risk profile and clinical indications.

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