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Original Research Article

COMPARATIVE EVALUATION OF THE EFFICACY OF ORMELOXIFENE AND NORETHISTERONE IN ABNORMAL UTERINE BLEEDING

A.V. Shanmuga Sundhari[1], V.S. Thamizharasi[2], Dheepa. C[2]

[1]Assistant Professor, Department of Obstetrics and Gynaecology, Government Medical College, Omadurar Government Estate, Chennai, Tamilnadu, India
[2]Senior Resident, Department of Obstetrics and Gynaecology, Government Medical College, Omadurar Government Estate, Chennai, Tamilnadu, India
[3]Senior Assistant Professor, Department of Obstetrics and Gynaecology, Government Medical College, Omadurar Government Estate, Chennai, Tamilnadu, India

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Corresponding Author:
Dr. A.V. Shanmuga Sundhari,
Email: shanmugasundhariav@gmail.com

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ABSTRACT

Background: Abnormal uterine bleeding (AUB) is common in reproductive and perimenopausal women, often causing heavy bleeding, anaemia, and a reduced quality of life. This study compared the efficacy and safety of ormeloxifene, a selective oestrogen receptor modulator, and norethisterone, a synthetic progestogen, in managing AUB. **Materials and Methods:** A randomised controlled study was conducted on 120 women with AUB, who were assigned to receive either ormeloxifene (n = 60; 60 mg twice weekly for 12 weeks, then once weekly for 12 weeks) or norethisterone (n = 60; 5 mg twice daily for 21 days per cycle for six cycles). Pictorial Blood Loss Assessment Chart (PBAC) scores, haemoglobin levels, serum ferritin, endometrial thickness, clots, dysmenorrhoea, and adverse effects were recorded at baseline, 1, 3, and 6 months. **Result:** Most participants were aged 40–49 years [ormeloxifene 26(43.3%); Norethisterone 29(48.3%)]. Baseline haemoglobin was 8.98±0.68 g/dL vs. 9.01±0.67 g/dL, and the PBAC score was 11.18±0.93 vs. 11.46 ± 0.96 for ormeloxifene and Norethisterone, respectively. At 6 months, haemoglobin levels were higher in the ormeloxifene group (11.9±1.54 g/dL vs. 11.1±0.59 g/dL; P=0.008). PBAC scores decreased to 7.43±0.72 vs. 8.17±0.94 (P=0.001), and serum ferritin reduced to 81.83±12.93 ng/mL vs. 99.27±14.75 ng/mL (P=0.001). The passage of clots post-treatment was 13.3% vs. 26.6%, and dysmenorrhoea was 8.3% vs 28.3%. Adverse effects were mild; amenorrhoea occurred in 6(10%) with ormeloxifene and none with norethisterone. **Conclusion:** Both drugs effectively managed AUB, but ormeloxifene showed better improvements in haemoglobin levels, menstrual blood loss, symptom relief, and tolerability. Larger multicentre studies with longer follow-up periods are recommended.

INTRODUCTION

Abnormal uterine bleeding (AUB) is a frequent gynaecologic problem affecting women of reproductive and perimenopausal ages. It encompasses any departure from regularity, duration, or volume of menstrual blood loss in the absence of pregnancy and serious organic pathology, and includes what was formerly termed dysfunctional uterine bleeding (DUB).[1] Heavy menstrual bleeding in AUB may lead to iron deficiency anaemia, affect quality of life, increase health care costs, and potentially necessitate surgical intervention if medical management fails.[2]

Among the medical treatments, norethisterone, a synthetic progestogen, has long been used. It acts by opposing oestrogen-driven endometrial proliferation, promoting endometrial maturation, stabilising vasculature, and reducing menstrual blood loss. Clinical study has shown norethisterone to be effective in the acute control of haemorrhage and in improving haemoglobin levels in adolescent and adult AUB cases.[3] However, its use is associated with adverse effects such as breakthrough bleeding, weight changes, mood disturbances, breast tenderness, and in some cases, metabolic or hepatic changes, particularly at higher doses or prolonged use.[4]

Ormeloxifene is a selective oestrogen receptor modulator (SERM). Ormeloxifene exerts both oestrogenic and anti-oestrogenic effects depending on the target tissue. In the endometrium, it exhibits antagonistic effects that slow proliferative growth and reduce thickness, hence reducing menstrual

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blood loss; in contrast, in bone and certain other tissues, it may have estrogen-like activity, which helps avoid some negative effects seen with unopposed estrogen or high-dose progestogens.[5] Several studies (pilot, randomised, open-label) in India show ormeloxifene to reduce blood loss (often measured by PBAC score), raise haemoglobin levels, and reduce endometrial thickness more significantly compared to norethisterone, with better patient compliance and fewer side effects.[6-8]

A recent meta-analysis of non-structural AUB treatments compared ormeloxifene with conventional hormonal therapies and found that ormeloxifene achieved better improvements in menorrhagia and haemoglobin levels than hormonal regimens, with an acceptable safety profile.[9] However, many existing studies are limited by small sample size or short follow-up, and adverse effects for both drugs are variably reported. In particular, data directly comparing ormeloxifene and norethisterone in the same population, looking comprehensively at efficacy (blood loss, haemoglobin, endometrial thickness) and adverse effects over a reasonable treatment period, are relatively few.[10]

Therefore, this study was designed to compare the efficacy of ormeloxifene and norethisterone in managing AUB and to assess the adverse effects of these drugs. The efficacy of ormeloxifene in AUB was compared with that of norethisterone in terms of reduction of menstrual blood loss, improvement in haemoglobin levels, changes in endometrial thickness, and documentation and comparison of the adverse effects of both agents in the treated population.

MATERIALS AND METHODS

Study design and setting: This randomised controlled study was conducted on 120 women presenting with AUB at the Outpatient Department of Obstetrics and Gynaecology. The Institutional Ethics Committee approved the study before it began, and written informed consent was obtained from all participants.

Inclusion Criteria

Women of reproductive age presenting with excessive, prolonged, or frequent menstrual bleeding without evidence of systemic or pelvic organ pathology were included.

Exclusion Criteria

Women with postmenopausal bleeding, fibroid uterus, adenomyosis, cervical or endometrial polyps, severe cervical dysplasia, atypical endometrial hyperplasia, malignancy, or pregnancy were excluded.

Methods: After enrolment, the participants were randomly assigned to two groups, the ormeloxifene group and the Norethisterone group, with 60 women in each group using a single-blinded randomisation method. The ormeloxifene group received 60 mg ormeloxifene twice a week for 12 weeks, followed by 60 mg ormeloxifene once a week for the next 12 weeks. The norethisterone group received 5 mg twice daily for 21 days, followed by 7 days of withdrawal for six cycles.

Detailed menstrual and medical histories were obtained from all participants. General examination was performed to assess anaemia, and pelvic examination was performed to rule out pregnancy, fibroids, adenomyosis, or other pelvic pathologies. Baseline investigations, including haemoglobin, total and differential leukocyte count, platelet count, bleeding and clotting time, and thyroid profile, were performed to exclude any bleeding disorders or subclinical hypothyroidism. Ultrasound was used to measure endometrial thickness and rule out other pelvic pathologies.

All participants were instructed to maintain a menstrual diary to record the number of bleeding days, sanitary pad usage, degree of soiling, clot size and number, presence of menstrual cramps, and other symptoms. Menstrual blood loss was assessed using the Pictorial Blood Loss Assessment Chart (PBAC) at each visit. A PBAC score of ≥ 100 was considered diagnostic of menorrhagia. Follow-up visits were scheduled at 1, 3, and 6 months to assess changes in the PBAC score, haemoglobin levels, and endometrial thickness.

Sample size

The minimum sample size was calculated using Open Epi version 3.01, with an alpha error of 5% and a power of 80%. The required sample size was determined to be 60 participants per group, for a total of 120 participants.

Statistical analysis

All data were organised in Microsoft Excel and analysed using IBM SPSS v22. Continuous variables are expressed as mean ± standard deviation, and categorical variables are expressed as counts and percentages. Comparisons between the two groups were performed using an independent sample t-test for continuous variables and the chi-square test for categorical variables. Statistical significance was set at $P < 0.05$.

RESULTS

The age distribution showed that most participants were aged 40–49 years (ormeloxifene 26, 43.3%; norethisterone 29, 48.3%) and fewer were in younger age groups (<20 years: 7, 11.6% vs 10, 16.7%; 20–30 years: 13, 21.6% vs 10, 16.7%; 30–40 years: 14, 23.3% vs 11, 23.3%). Parity patterns were comparable, with Para 2 being most common (29, 48.3% vs 26, 43.3%), followed by Para ≥3 (15, 25% vs 17, 28.3%), Para 1 (12, 20% vs 14, 23.3%), and nulligravida (4, 6.7% vs 3, 5%). The duration of menstrual flow was predominantly 5–7 days in both groups (57, 95%), with very few having 2–5 days (2, 3.3%) or >7 days (1, 1.7%) [Table 1].

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Table 1: Comparison of baseline demographic and menstrual characteristics

Parameter	Category	Ormeloxifene	Norethisterone
Age (years)	<20	7 (11.6%)	10 (16.7%)
	20–30	13 (21.6%)	10 (16.7%)
	30–40	14 (23.3%)	11 (23.3%)
	40–49	26 (43.3%)	29 (48.3%)
Parity	Nulligravida	4 (6.7%)	3 (5%)
	Para 1	12 (20%)	14 (23.3%)
	Para 2	29 (48.3%)	26 (43.3%)
	Para ≥3	15 (25%)	17 (28.3%)
Duration of flow (days)	<2	0	0
	2–5	2 (3.3%)	2 (3.3%)
	5–7	57 (95%)	57 (95%)
	>7	1 (1.7%)	1 (1.7%)

Haemoglobin levels were comparable at baseline (ormeloxifene 8.98 ± 0.68 g/dL, norethisterone 9.01 ± 0.67 g/dL; P = 0.787), 1 month (9.38 ± 0.71 vs. 9.40 ± 0.66; P = 0.915), and 3 months (10.38 ± 0.58 vs. 10.38 ± 0.61; P = 0.976), but were higher in the ormeloxifene group at 6 months (11.9 ± 1.54 vs. 11.1 ± 0.59; P = 0.008). Menstrual blood loss decreased in both groups, with ormeloxifene showing lower values at 3 months (9.27 ± 0.78 vs. 9.58 ± 0.82; P = 0.040) and 6 months (7.43 ± 0.72 vs. 8.17 ± 0.94; P = 0.001). Serum ferritin levels also declined over time, being lower in the ormeloxifene group at 3 months (111.75 ± 15.09 vs 118.62 ± 18.00; P = 0.025) and 6 months (81.83 ± 12.93 vs 99.27 ± 14.75; P = 0.001) [Table 2].

Table 2: Comparison of haematological and menstrual parameters

Parameter	Time point	Ormeloxifene	Norethisterone	P value
Haemoglobin (g/dL)	Baseline	8.98 ± 0.68	9.01 ± 0.67	0.787
	1 month	9.38 ± 0.71	9.40 ± 0.66	0.915
	3 months	10.38 ± 0.58	10.38 ± 0.61	0.976
	6 months	11.9 ± 1.54	11.1 ± 0.59	0.008
Menstrual blood loss (mL)	Baseline	11.18 ± 0.93	11.46 ± 0.96	0.108
	1 month	10.27 ± 0.83	10.42 ± 0.86	0.339
	3 months	9.27 ± 0.78	9.58 ± 0.82	0.040
	6 months	7.43 ± 0.72	8.17 ± 0.94	0.001
Serum ferritin (ng/mL)	Baseline	242.72 ± 33.74	249.93 ± 31.21	0.226
	1 month	157.77 ± 22.81	153.17 ± 19.89	0.241
	3 months	111.75 ± 15.09	118.62 ± 18.00	0.025
	6 months	81.83 ± 12.93	99.27 ± 14.75	0.001

Adverse effects were generally mild in both groups. Amenorrhea occurred in 6 participants (10%) in the ormeloxifene group and none in the Norethisterone group. Intermenstrual bleeding was reported in 2 (3.3%) vs 5 (8.3%) participants, and weight gain in 1 (1.7%) vs 5 (8.3%). Headache occurred in 3 (5%) and 2 (3.3%) participants, and nausea in 3 (5%) and 7 (11.6%) participants in the ormeloxifene and norethisterone groups, respectively [Table 3].

Table 3: Comparison of adverse effects between groups

Adverse effect	Subtype	Ormeloxifene	Norethisterone
Amenorrhoea	Yes	6 (10%)	0
	No	54 (90%)	60 (100%)
Intermenstrual bleeding	Yes	2 (3.3%)	5 (8.3%)
	No	58 (96.6%)	55 (91.6%)
Weight gain	Yes	1 (1.7%)	5 (8.3%)
	No	59 (98.3%)	55 (91.6%)
Headache	Yes	3 (5%)	2 (3.3%)
	No	57 (95%)	58 (96.6%)
Nausea	Yes	3 (5%)	7 (11.6%)
	No	57 (95%)	53 (88.3%)

Before treatment, most participants experienced passage of clots (ormeloxifene 52, 86.7%; Norethisterone 56, 93.3%) and dysmenorrhoea (34, 56.7%; 31, 51.7%). After treatment, symptoms decreased in both groups, with fewer participants reporting clots (ormeloxifene, 8, 13.3%; norethisterone, 16, 26.6%) and dysmenorrhoea (5, 8.3%; 17, 28.3%) [Table 4].

Table 4: Effect of groups on passage of clots and dysmenorrhea

Drug	Time period	Passage of clots	Dysmenorrhea
Ormeloxifene	Pre-treatment	52 (86.7%)	34 (56.7%)
	Post-treatment	8 (13.3%)	5 (8.3%)
Norethisterone	Pre-treatment	56 (93.3%)	31 (51.7%)
	Post-treatment	16 (26.6%)	17 (28.3%)

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DISCUSSION

In our study, most participants were in the 40–49 years age group, with Para 2 being the most common parity. The majority of women reported a menstrual flow duration of 5–7 days, with few having shorter or longer cycles. Similarly, Cardoso et al. reported comparable baseline features in both groups, including mean age (44.2 vs. 45.3 years), mean parity (4 each), and mean duration of symptoms (8.4 vs. 7.6 months).[11] Additionally, Chitrangada et al. also reported comparable demographic findings, with a mean age of approximately 40 years in both groups (40.18 ± 4.52 vs. 40.2 ± 4.56) and similar parity (2.8 ± 0.85 vs. 2.8 ± 0.78).[12] Likewise, Agarwal et al. reported a mean age of 38.3 years in the ormeloxifene group and 39.1 years in the Norethisterone group. Mean parity was three in both groups, and mean duration of symptoms was similar (9.4 vs. 9.6 months).[13]

Similarly, Das et al. reported that most patients were aged 40–55 years, with 38% in the 40–45 years age group and 32–36% in the 46–55 years age group. Higher parity was common, with 42% vs. 44% of the women being Para ≥4. Mean duration of symptoms was around 6 months in both groups.[14] Also, Fatima et al. reported age mostly 30–50 years, baseline PBAC ~202–216, haemoglobin 8.35–8.50 g/dL, and endometrial thickness 10.81–11.08 mm.15 The baseline demographic and menstrual characteristics of participants in our study were similar to those reported in previous studies, with most women in the 40–49 years age group, Para 2 being most common, and comparable menstrual patterns.

In our study, haemoglobin levels were similar between the groups initially and at early follow-up but improved more in the ormeloxifene group by 6 months. Menstrual blood loss decreased in both groups, with a greater reduction in the ormeloxifene group. Serum ferritin levels declined over time in both groups, remaining lower in the ormeloxifene group at later follow-ups. Likewise, Cardoso et al. reported that haemoglobin levels increased from 8.52 to 10.5 g/dL with ormeloxifene vs 8.28 to 8.7 g/dL with norethisterone. PBAC scores decreased from 224 to 80 vs 253 to 165, and endometrial thickness reduced from 12.09 to 8.2 mm vs 12.07 to 10.8 mm.[11] Similarly, Chitrangada et al. observed haemoglobin rising from 7.27 to 8.99 g/dL with ormeloxifene and from 7.42 to 8.33 g/dL with norethisterone at 6 months; PBAC scores decreased by 59.5% vs 43.25%, showing significant differences at 4 and 6 months.[12]

In addition, Agarwal et al. found baseline haemoglobin comparable (7.52 vs. 7.48 g/dL), rising to 10.4 g/dL with ormeloxifene vs 8.6 g/dL with norethisterone by 6 months; PBAC scores reduced from 216 to 84 vs 232 to 170, and endometrial thickness decreased from 12.12 to 8.4 mm vs 12.05 to 9.8 mm.13 Moreover, Bhattacharyya et al. reported haemoglobin rising from 8.49 to 11.02 g/dL with ormeloxifene, PBAC decreasing from 108.7 to 62.48, and endometrial thickness falling from 6.5 to 5.3 mm, outperforming norethisterone and placebo.[16]

Similarly, Das et al. observed a mean haemoglobin level of 9.8 vs 8.2 g/dL, PBAC of 90 vs 190, and endometrial thickness of 7.6 vs 10.5 mm (all $P < 0.001$) after 3 months.[14] Similarly, Fatima et al. showed haemoglobin levels rising from 8.50 to 9.2 g/dL with ormeloxifene vs 8.35 to 8.63 g/dL with norethisterone; PBAC decreased from 202.44 to 122.22 vs 215.86 to 162.16, and endometrial thickness reduced from 11.08 to 7.60 mm vs 10.81 to 9.05 mm.[15] Ormeloxifene led to greater improvements in haemoglobin, larger reductions in menstrual blood loss, and more pronounced decreases in endometrial thickness compared to norethisterone, consistent with findings from previous studies.

In our study, the adverse effects were generally mild in both groups. Amenorrhea occurred only with ormeloxifene, while intermenstrual bleeding, weight gain, headache, and nausea were observed in both groups with varying frequency. Similarly, Chitrangada et al. reported fewer side effects with ormeloxifene, with breakthrough bleeding and spotting occurring only in norethisterone users (14% and 8%), while amenorrhea and hypomenorrhea were more common with ormeloxifene.[12] Likewise, Bhattacharyya et al. observed amenorrhea (36.4%), spotting (9.1%), hypomenorrhea (9.1%), and stress urinary incontinence (18.2%) in the ormeloxifene group, whereas breakthrough bleeding occurred in 12.5% of Norethisterone users, and spotting was most frequent in the placebo group.[16]

Additionally, Das et al. reported side effects in 38% of ormeloxifene users and 50% of norethisterone users, with nausea (16% vs. 20%) and headache (10% vs. 12%) common in both, and spotting more frequent with Norethisterone (10%).[14] Similarly, Fatima et al. found that 86% of ormeloxifene users experienced no side effects compared to 66% with norethisterone, while nausea, weight gain, and headache were more frequent in the norethisterone group.[15] Both drugs were generally well tolerated, with ormeloxifene showing fewer and milder side effects compared to norethisterone.

In our study, most participants initially experienced passage of clots and dysmenorrhea. After treatment, these symptoms decreased in both groups, with greater relief observed in the ormeloxifene group. Similarly, Agarwal et al. found that a higher proportion of patients in the ormeloxifene group reported marked improvement (88% vs. 74%).[13] Similarly, Fatima et al. reported marked improvement in 76% of ormeloxifene users vs. 38% with norethisterone.15 In addition, Bhattacharyya et al. found that 81.67% of women in the ormeloxifene group reported marked subjective improvement, compared to only 11.67% in the norethisterone group, while 73.33% of norethisterone users reported no improvement.[16] Ormeloxifene provided greater relief from passage of clots and dysmenorrhoea,

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showing more marked symptom improvement than norethisterone.

Limitations: This study was conducted at a single centre and relied on self-reported menstrual diaries, which may have introduced reporting bias. Additionally, the follow-up period was limited to 6 months, restricting the assessment of long-term efficacy and safety.

CONCLUSION

Ormeloxifene and norethisterone both effectively reduced menstrual blood loss, improved haemoglobin levels, and decreased dysmenorrhea in women with AUB. Ormeloxifene demonstrated slightly greater improvements in haematological parameters and symptom relief, with fewer adverse effects, suggesting that it may be a more effective and better-tolerated option for managing AUB. Future studies with larger, multicentre populations and longer follow-up are recommended to confirm the long-term efficacy and safety.

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