**International Journal of Medical and Pharmaceutical Research**

Online ISSN-2958-3683 | Print ISSN-2958-3675
Frequency: Bi-Monthly
Available online on: https://ijmpr.in/

Original Article

# Efficacy of Ormeloxifene Versus Norethisterone in Selected Group of Patients with Abnormal Uterine Bleeding – A Comparative Study

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*Received: 07-12-2025*
*Accepted: 03-01-2026*
*Available online: 16-01-2026*



## ABSTRACT

**Background:** Norethisterone, is the most frequently prescribed drug for AUB serving 38% of the patient population, for cost effectiveness and less side effects. Ormeloxifene, a SERM, mediates its effects by high affinity interaction with ER, antagonizing the effects of oestrogen on uterine and breast tissue and stimulating effects on vagina, bone, CVS and CNS. The present study has been conducted to compare the efficacy of Ormeloxifene, especially the reduction of menstrual blood loss and reduction of Endometrial Thickness, with Norethisterone, in the treatment of AUB.

**Objective:** The objective was to assess the efficacy of Ormeloxifene in Reduction of Blood Loss as per PABC Score and to compare it with Norethisterone.

**Method:** Total 60 women were studied in 2 groups: GROUP A (Ormeloxifene – Case/Study) - 60 mg of Ormeloxifene tablet twice weekly x 6 months for 30 subjects and GROUP B (Norethisterone - Control)- 5 mg of Norethisterone tablet twice daily from day 1 to day 21 x 6 months for 30 subjects.

**Results:** We found that in group-B (Norethisterone), the mean value of PBAC Score at day 0, 3 months and 6 months were significantly higher than group-A(Ormeloxifene) and difference of mean PBAC Scores in two groups were also statistically significant ($p<0.001$). In group-B (Norethisterone), the mean value of endometrial thickness and difference of mean endometrial thickness at 6 months were significantly higher than group-A (Ormeloxifene) which were statistically significant ($p<0.001$).

**Conclusion:** Ormeloxifene can be considered as an effective and safe therapeutic option for the medical management of DUB, as the reduction in menstrual blood loss (PABC Score), rise in Haemoglobin concentration and decrease in Endometrial Thickness were significantly more with Ormeloxifene than Norethisterone.

***Keywords****: Ormeloxifene, Norethisterone, PABC Score, AUB.*

## INTRODUCTION

Disorders of menstruation account for the most common reason for a gynaecological consultation among women. DUB, abnormal uterine bleeding during menstrual cycle in the absence of organic pelvic pathology, is one such condition, most commonly affecting women from extremes of reproductive age group.

Treatment options range from offering medical measures such as Cyclooxygenase inhibitors, Tranexamic acid, hormonal agents and in cases not managed by medical therapy, offering surgical management.

Ormeloxifene, developed as Centchroman by CDRI, Lucknow and it is marketed as 'Saheli' and 'Sevista', available free of cost by Govt of India as 'Chhaya', a Selective Estrogen Receptor Modulator, is a non-steroidal, non-hormonal oral contraceptive. It mediates its effects by high affinity interaction with oestrogen receptors, antagonizing

the effect of oestrogen on uterine and breast tissue and stimulating effect on vagina, bone, cardiovascular system and central nervous system.

Norethisterone, a conventional Progesterone, is the most frequently prescribed drug for abnormal uterine bleeding serving 38% of the patient population, the reason being cost effectiveness and absence of side effects. It suppresses endometrial development, re-establish predictable bleeding patterns, decrease menstrual flow and lower the risk of iron deficiency anaemia.

Few studies, e.g. Patel et al, Kriplani et al, Chauhan et al, have shown the effectiveness of Ormeloxifene in the management of Abnormal or Dysfunctional Uterine Bleeding, and in comparison, it has been found superior to Norethisterone.

The present study has been conducted to compare the efficacy of Ormeloxifene, especially the reduction of menstrual blood loss, with the commonly used progesterone derivative Norethisterone, in the treatment of AUB.
***Research Hypothesis:*** The reduction in menstrual blood loss, rise in Haemoglobin concentration and decrease in endometrial thickness are significantly more with Ormeloxifene than Norethisterone.

**OBJECTIVE**
The main objective of this study was to assess the efficacy of Ormeloxifene in Reduction of Blood Loss as per PABC Score and to compare it with Norethisterone.

**METHODS**
➢**PLACE OF STUDY -** Department of Obstetrics and Gynaecology in MGM Medical College and LSK Hospital, Kishanganj, Bihar – 855107

➢**STUDY DESIGN -** Prospective Cohort Study**.**

➢**PERIOD OF STUDY -** March 2021 to August 2022 (18 Months).

➢**STUDY POPULATION -** The study population comprised of patients being treated for AUB in the Department of OB_GYN, MGM Medical College and LSK Hospital, Kishanganj by administration of Ormeloxifene and Norethisterone in OPD and Indoor.

➢**INCLUSION CRITERIA -** Women in the age group 30 to 40 years who attended OPD with Symptoms of Heavy Menstrual Bleeding, defined as >80ml bleeding per menstrual cycle.

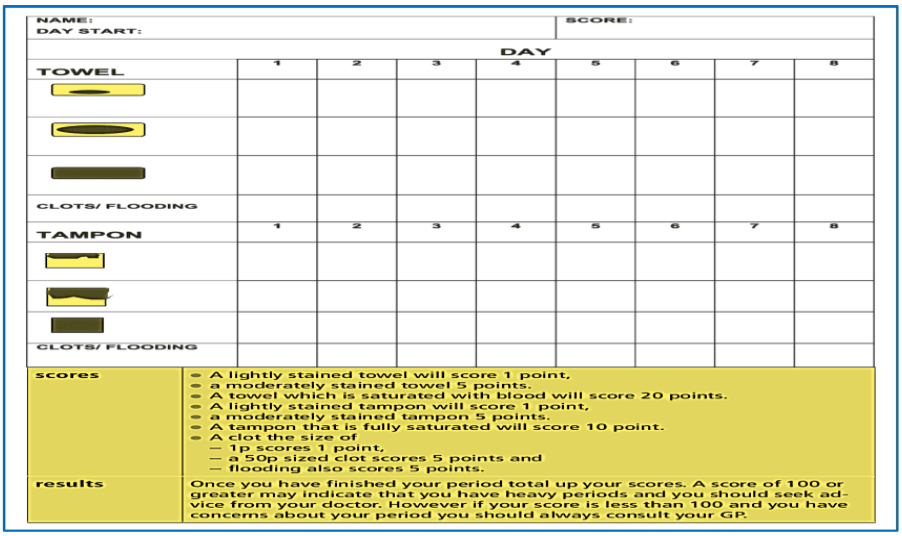
➢**EXCLUSION CRITERIA -**
Postmenopausal bleeding, Endometrial biopsy suggestive of atypical hyperplasia or Ca, Cervical dysplasia, Bleeding dyscrasia, Clinical evidence of jaundice or hepatic dysfunction, Hypersensitivity to the drugs, Uterine size >6 weeks pregnant uterus, Women desirous of fertility, History of abortion, Endometrial polyp, Adenomyosis

➢**SAMPLE SIZE –** 60 patients. Every alternate patient will be allocated to:

GROUP A (Ormeloxifene – Case/Study) - 60 mg of Ormeloxifene tablet twice weekly x 6 months for 30 subjects.

GROUP B (Norethisterone - Control)- 5 mg of Norethisterone tablet twice daily from day 1 to day 21 x 6 months for 30 subjects.

➢**LABORATORY INVESTIGATIONS**
Routine Blood examination, USG, PBAC scoring (Pictorial Blood loss Assessment Chart)




**Pictorial blood assessment chart and scoring system (PBAC)**

➢ **STATISTICAL ANALYSIS PLAN**: Data is collected and statistically analysed using SPSS 25 (SPSS Inc, Chicago, IL, USA). Data will be summarized as mean and standard deviation for numerical variables and count and percentages for categorical variables. Two-sample t-tests for a difference in mean involved independent samples or unpaired samples. Paired t-tests will be a form of blocking and had greater power than unpaired tests. A chi-squared test ($\lambda^2$test) will be any statistical hypothesis test wherein the sampling distribution of the test statistic is a chi- squared distribution when the null hypothesis is true. Without other qualification, 'chi- squared test' often is used as short for Pearson's Chi- squared test. Unpaired proportions will be compared by Chi-square test or Fischer's exact test, as appropriate.

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 favour of the alternative hypothesis. *p*-value ≤ 0.05 will be considered for statistically significant.

**RESULTS**

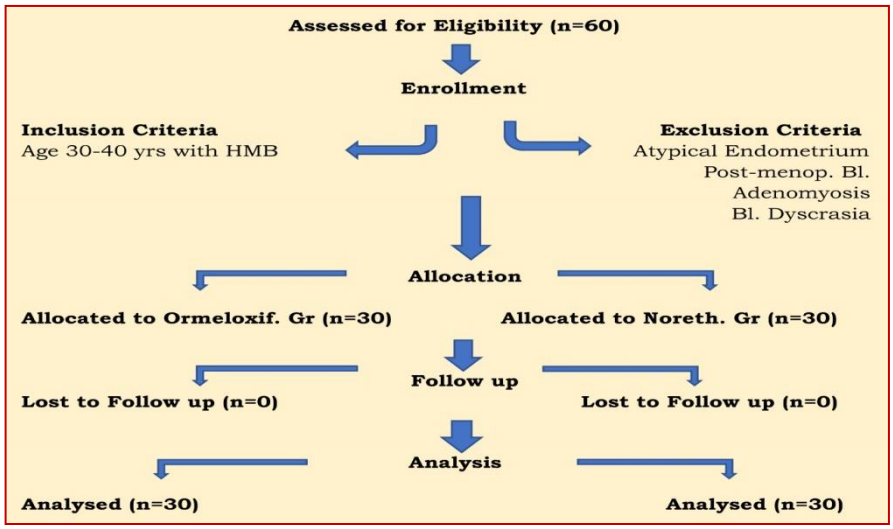



**Table 1: Distribution of mean PBAC score at different intervals**

| | | Number | Mean | SD | Minimum | Maximum | Median | p-value |
|---|---|---|---|---|---|---|---|---|
| **PBAC Score day 0** | Group-A (Ormeloxifene) | 30 | 361.8000 | 14.6814 | 340.0000 | 390.0000 | 360.0000 | <0.001 |
| | Group-B (Norethisterone) | 30 | 376.8667 | 11.3220 | 360.0000 | 390.0000 | 380.0000 | |
| **PBAC Score at 3 month** | Group-A (Ormeloxifene) | 30 | 106.3667 | 3.2429 | 98.0000 | 110.0000 | 107.0000 | <0.001 |
| | Group-B (Norethisterone) | 30 | 112.5000 | 2.0299 | 107.0000 | 116.0000 | 112.0000 | |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **PBAC Score at 6 month** | Group-A (Ormeloxifene) | 30 | 69.2000 | 3.4481 | 62.0000 | 75.0000 | 69.0000 | <0.001 |
| | Group-B (Norethisterone) | 30 | 109.4000 | 2.5542 | 104.0000 | 113.0000 | 109.5000 | |

In group-B (Norethisterone), the mean value of PBAC Score at day 0 was significantly higher than group-A(Ormeloxifene) and difference of mean PBAC Score at day 0 in two groups was statistically significant (p<0.001).In group-B (Norethisterone), the mean value of PBAC Score at day 3 month was significantly higher than group-A(Ormeloxifene) and difference of mean PBAC Score at day 3 month in two groups was statistically significant (p<0.001).In group-B (Norethisterone), the mean value of PBAC Score at day 6 month was significantly higher than group-A(Ormeloxifene) and difference of mean PBAC Score at day 6 month in two groups was statistically significant (p<0.001).

**Table 2: Distribution of mean ET at different intervals**

| | | Number | Mean | SD | Minimum | Maximum | Median | p-value |
|---|---|---|---|---|---|---|---|---|
| **Endometrial thickness (mm) day 0** | Group-A (Ormeloxifene) | 30 | 11.4733 | .8614 | 10.0000 | 13.0000 | 11.4500 | 0.088 |
| | Group-B (Norethisterone) | 30 | 11.0800 | .8919 | 10.0000 | 13.0000 | 11.0000 | |
| **Endometrial thickness (mm) day 3 month** | Group-A (Ormeloxifene) | 30 | 9.3333 | .8474 | 8.2000 | 11.0000 | 9.4000 | 0.080 |
| | Group-B (Norethisterone) | 30 | 9.6800 | .6462 | 8.3000 | 11.0000 | 9.8000 | |
| **Endometrial thickness (mm) day 6 month** | Group-A (Ormeloxifene) | 30 | 6.7300 | 2.1560 | 5.0000 | 12.0000 | 6.0000 | 0.001 |
| | Group-B (Norethisterone) | 30 | 8.5900 | 2.0028 | 0.9000 | 12.0000 | 9.0000 | |

Difference of mean endometrial thickness at day 0 in two groups was not statistically significant (p=0.088).In group-B (Norethisterone), the mean value of endometrial thickness at day 3 month was significantly higher than group-A(Ormeloxifene) and difference of mean endometrial thickness at day 3 month in two groups was not statistically significant (p=0.080).In group-B (Norethisterone), the mean value of endometrial thickness at day 6 month was significantly higher than group-A(Ormeloxifene) and difference of mean endometrial thickness at day 6 month in two groups was statistically significant (p=0.001).

**Table 3: Association between ET Increase vs Groups**

| GROUP | | | |
|---|---|---|---|
| **Endometrial thickness Increase** | **Group-A (Ormeloxifene)** | **Group-B (Norethisterone)** | **TOTAL** |
| **NO** Row % Col % | 26<br>47.3<br>86.7 | 29<br>52.7<br>96.7 | 55<br>100.0<br>91.7 |
| **YES** Row % Col % | 4<br>80.0<br>13.3 | 1<br>20.0<br>3.3 | 5<br>100.0<br>8.3 |
| **TOTAL** Row % Col % | 30<br>50.0<br>100.0 | 30<br>50.0<br>100.0 | 60<br>100.0<br>100.0 |

**p-value:** 0.161, Statistically not significant.

In Group-A(Ormeloxifene) 4(13.3%) patients had increased Endometrial thickness and in group-B (Norethisterone), 1(3.3%) patients had increased Endometrial thickness though it was not statistically significant.

**Table 4: Association between Amenorrhea vs Groups**

| GROUP | | | |
|---|---|---|---|
| **Amenorrhoea** | **Group-A (Ormeloxifene)** | **Group-B (Norethisterone)** | **TOTAL** |
| **No** Row % Col % | 29<br>50.9<br>96.7 | 28<br>49.1<br>93.3 | 57<br>100.0<br>95.0 |

| | | | |
|---|---|---|---|
| **Yes** Row<br>% Col % | 1<br>33.3<br>3.3 | 2<br>66.7<br>6.7 | 3<br>100.0<br>5.0 |
| **TOTAL** Row %<br>Col % | 30<br>50.0<br>100.0 | 30<br>50.0<br>100.0 | 60<br>100.0<br>100.0 |

**p-value:** 0.554

## DISCUSSION

We found that In group-B (Norethisterone), the mean value of PBAC Score at day 0 was significantly higher than group-A(Ormeloxifene) and difference of mean PBAC Score at day 0 in two groups was statistically significant (p<0.001).In group-B (Norethisterone), the mean value of PBAC Score at 3 month was significantly higher than group-A(Ormeloxifene) and difference of mean PBAC Score at 3 month in two groups was statistically significant (p<0.001).In group-B (Norethisterone), the mean value of PBAC Score at 6 month was significantly higher than group-A(Ormeloxifene) and difference of mean PBAC Score at 6 month in two groups was statistically significant (p<0.001).
In group-B (Norethisterone), the mean value of endometrial thickness at 3 months was significantly higher than group-A (Ormeloxifene) and difference of mean endometrial thickness at 3 months in two groups was statistically significant.
In group-B (Norethisterone), the mean value of endometrial thickness at 6 months was significantly higher than group-A (Ormeloxifene) and difference of mean endometrial thickness at 6 months in two groups was statistically significant (p=0.001).

*Swati Gett et al*[52] (2018) found that both Ormeloxifene and Norethisterone reduced menorrhagia, with a significant difference in PBAC scores (p value <0.05).

*Agarwal N et al*[53] (2013) found that the primary outcomes were reduction in menstrual blood loss [measured by fall in PBAC (Pictorial Blood loss Assessment Chart) score and subjective assessment], rise in haemoglobin level and decrease in endometrial thickness. The reduction in mean PBAC score with ormeloxifene (216 to 88) was significantly more than with norethisterone (262 to 162) at 3 months.

*Khan SA et al*[55] (2014) found that the mean hemoglobin concentration increased significantly from 8.1to 9.4 gms/dl with a rise of 1.3gm/dl (p< 0.05). The mean pretreatment endometrial thickness was 11mm and it decreased significantly to 8.4mm after 6 months of treatment with ormeloxifene (p < 0.05).

*Shahab SF et al*[58] (2014) found that norethisterone group had marked relief of symptoms with significant reduction of blood clots, reduction of Pictorial Blood Assessment Chart (PBAC) scores (=25.36, P value=0.0001, extremely significant).

*Sawarkar U et al*[59] (2018) found that after the intervention, 76.8% of women achieved a duration of bleeding of 4–5 days, and in 87% of women, menstrual cycle became regular. Mean Hb concentration of study participants increased by 0.5 g/dl at the end of the study.

*Karmakar S et al*[60] (2016) found that the mean PBAC score and Endometrial thickness (ET) in Norethisterone group and ormeloxifene group reduced significantly (P - value <0.0001) at the end of 3rd month after treatment were stopped. The Hb level increased maximum in Ormeloxifene group followed by Norethisterone group significantly (p<0.0001).

*Mohakul SK et al*[61] (2017) found that Excellent response to the treatment was noticed in most. 57.14% were pain free at the end of one month; 82.14% by the end of second month, and a whopping 92.8% had no pain by the end of third month. 4.8% persisted with mild pain.

*Masand D et al*[63] (2015) found that the mean pre-treatment MBL (PBAC score) was 343.13 (140-765), which reduced to 222.22 (80-398) at 1 months and 90.0 (0-340) at 3 months with treatment. By end of 6 months, the mean PBAC score was 68.84 (0-320). There was a significant reduction in MBL in patients on ormeloxifene (p-value ≤ 0.001). The rise in haemoglobin and decrease in ET, in women on ormeloxifene was also statistically significant (p value<o.oo1).

*Amruta C et al*[64] (2018) found that Ormeloxifene showed a better reduction in mean PBAC score (225 to 75) compared to norethisterone (234 to 110) at 6 months (p<0.01).

*Ravibabu K et al*[66] (2017) found that there was significant decrease in median PABC score from baseline to 25th week of treatment follow-up and the reduction was found to be statistically significant ( p<0.001).

*Singh HO et al*[67] (2015) found that the median difference between pre-treatment and post- treatment PBAC score was found to be significant.

*Gandotra N et al*[68] (2016) found that there was a significant reduction in mean PBAC score from 316 to 52 after six months of treatment. The mean hemoglobin concentration increased significantly from 8.4 to 9.8 gms/dl with a rise of 1.4gm/dl (p <0.05). The mean pre-treatment endometrial thickness was 10.8mm and it decreased significantly to 8.1mm after 6 months of treatment with ormeloxifene (p < 0.05).

Therefore, Ormeloxifene can be considered as an effective and safe therapeutic option for the medical management of dysfunctional uterine bleeding.

## CONCLUSION

We found in our study:

1. Both the arms (Ormeloxifene and Norethisterone) showed:
   (i) reduction in PBAC score,
   (ii) rise in hemoglobin level and
   (iii) reduction in endometrial thickness.

But, the reduction in menstrual blood loss (PABC Score), rise in Haemoglobin concentration and decrease in endometrial thickness are significantly more with Ormeloxifene than Norethisterone in the management of AUB.

2. While discussing about the side effects, no major side effects were seen with either of the drugs.
3. Ormeloxifene has better compliance and acceptability with marked relief in symptoms.
4. Although the sample size is small, it reflects advantage of Ormeloxifene in reducing Heavy Menstrual Bleeding when compared to Norethisterone.

## LIMITATIONS

There are limitations in the present study despite our sincere efforts:

1. The study has been done in a single center, hence the generalization is not possible.
2. The sample size was small. Only 60 cases are not enough for this kind of study. Randomized Control Studies (RCTs) with larger number of patients are needed to verify the findings and come to a definite conclusion.

## CONFLICTS

There were no conflicts in our study.

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