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ORMELOXIFENE VERSUS TRANEXAMIC ACID IN THE TREATMENT OF ABNORMAL UTERINE BLEEDING: A COMPARATIVE STUDY IN A TERTIARY CARE TEACHING INSTITUTE

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ABSTRACT **Background:** Abnormal uterine bleeding (AUB) is a frequent gynaecological complaint and a common cause of anaemia and reduced quality of life. Medical treatment is preferred in many women who need symptom control without immediate surgery. **Objective:** To compare ormeloxifene and tranexamic acid in terms of reduction in menstrual blood loss, improvement in haemoglobin and tolerability in women with AUB. **Methods:** This prospective comparative observational study was conducted at Amaltas Institute of Medical Sciences, Dewas, from October 2022 to February 2024. One hundred and fifty women aged 18-50 years with clinically diagnosed AUB were included and divided into two groups of 75 each. Group O received ormeloxifene 60 mg twice weekly for three months followed by once weekly for three months. Group TA received tranexamic acid 500 mg three times daily during the first three days of menstruation for six months. PBAC score and haemoglobin were assessed at baseline, three months and six months. **Results:** Baseline PBAC scores were comparable in Group O and Group TA (155 ± 8.38 vs. 154 ± 9.22; p = 0.380). At six months, PBAC score reduced to 58 ± 12.6 with ormeloxifene and 69.7 ± 12.4 with tranexamic acid ($p < 0.0001$). Mean haemoglobin increased from 9.32 ± 1.00 to 11.7 ± 1.07 g/dL in Group O and from 9.12 ± 0.96 to 10.8 ± 1.11 g/dL in Group TA ($p < 0.001$). No serious adverse event was observed. **Conclusion:** Both drugs were effective, but ormeloxifene produced greater reduction in menstrual blood loss and better haemoglobin improvement over six months.

KEYWORDS : Abnormal Uterine Bleeding; Ormeloxifene; Tranexamic Acid; Haemoglobin

INTRODUCTION

Abnormal uterine bleeding (AUB) is among the most common reasons for gynaecological outpatient consultation. It refers to bleeding from the uterine corpus that is abnormal in volume, frequency, regularity or duration and occurs in the absence of pregnancy [1]. In routine clinical practice, women may present with heavy menstrual bleeding, prolonged menstrual bleeding, intermenstrual bleeding or a combination of these patterns. The complaint is important not only because of the bleeding itself, but also because it may be associated with anaemia, fatigue, impaired work performance, social restriction and anxiety regarding fertility or underlying disease. Menstrual health is increasingly recognised as a public health issue rather than a minor inconvenience [2]. In the Indian setting, many women present late after months of heavy bleeding, often after self-medication or repeated short courses of haematinics. A practical medical regimen that is affordable, easy to explain and acceptable over several cycles can therefore reduce the clinical burden of anaemia and repeated visits.

The causes of AUB are heterogeneous. Ovulatory dysfunction and hormonal imbalance are frequent in adolescents, reproductive-age women and perimenopausal women. Structural abnormalities such as endometrial polyps, adenomyosis and leiomyoma can produce heavy or prolonged bleeding, while endometrial causes, coagulation disorders, iatrogenic factors and other systemic conditions also contribute in selected patients. The PALM-COEIN classification provides a practical framework for classifying structural and non-structural causes and supports a more uniform approach to diagnosis and reporting [3]. Careful history taking, clinical examination, baseline haemoglobin estimation, pregnancy exclusion and pelvic imaging where indicated are therefore essential before choosing therapy.

Untreated or persistent AUB can lead to iron-deficiency anaemia. The clinical consequences are often underestimated; women may experience tiredness, reduced exercise tolerance, dizziness, poor concentration and repeated healthcare visits. In settings where access to definitive surgical management is limited or where women wish to preserve fertility, effective medical therapy is especially valuable. Contemporary reviews and Cochrane evidence support several medical options for heavy menstrual bleeding, including antifibrinolytics, hormonal preparations, non-steroidal anti-inflammatory drugs and selective estrogen receptor modulators, depending on the clinical profile and contraindications [4,5].

Tranexamic acid is a non-hormonal antifibrinolytic drug. It inhibits conversion of plasminogen to plasmin and reduces fibrinolysis in menstrual blood, thereby limiting blood loss during the days of active bleeding. It is taken during menstruation rather than continuously, making it acceptable to many women. Randomized evidence supports its efficacy in heavy menstrual bleeding, although its effect is cycle-limited and dependent on use in each menstrual period [6,7].

Ormeloxifene is a selective estrogen receptor modulator with anti-estrogenic action on the endometrium. It is non-steroidal, orally administered and usually given twice weekly initially, followed by weekly dosing. It has been used in India for dysfunctional uterine bleeding and other AUB presentations, with studies reporting reduction in PBAC score, improvement in haemoglobin and acceptable tolerability [8,9]. Because ormeloxifene and tranexamic acid differ in mechanism, schedule and expected durability of effect, direct comparison is clinically useful. The present study was undertaken to compare these two drugs in women with AUB attending a tertiary care teaching institute, using PBAC score and haemoglobin change as objective outcomes. The specific objective was to assess whether either drug offered superior reduction in menstrual blood loss over six months and whether this reduction was accompanied by better correction of anaemia and acceptable safety in routine clinical use.

MATERIALS AND METHODS

This was a single-centre, hospital outpatient-based, prospective comparative observational study conducted in the Department of Obstetrics and Gynaecology, Amaltas Institute of Medical Sciences, Dewas, Madhya Pradesh. The study period was 18 months, from October 2022 to February 2024. The initial phase included protocol preparation, ethical approval and preparation of consent and data collection forms. Recruitment and follow-up were carried out over the major part of the study period, followed by data analysis and report writing. Institutional ethical clearance was obtained before enrolment, and written informed consent was taken from all participants.

Women aged 18-50 years with clinically diagnosed abnormal uterine bleeding were eligible. The diagnosis was based on menstrual history, clinical assessment and routine evaluation by the treating team. Women were excluded if they were pregnant or lactating, had a known clotting disorder, were taking anticoagulant medication, or had any medical or psychological condition that, in the opinion of the investigators, could compromise patient safety or interfere with assessment. The exclusion criteria were selected to reduce treatment-related risk and to avoid confounding from conditions that could independently alter bleeding.

At baseline, demographic details, menstrual cycle length, duration of

bleeding, duration of symptoms and bleeding pattern were recorded. Bleeding patterns included heavy menstrual bleeding, heavy and prolonged menstrual bleeding, cyclic midcycle intermenstrual bleeding, cyclic pre- or postmenstrual intermenstrual bleeding and acyclic intermenstrual bleeding. The likely diagnosis was classified using PALM-COEIN categories where applicable. Baseline PBAC score was recorded as the primary measure of menstrual blood loss. The PBAC was explained to participants as a record of the number of sanitary pads used and the degree of staining, so that menstrual blood loss could be followed in a reproducible manner. Haemoglobin was measured using standard laboratory methods and repeated during follow-up. Women were also asked about drug intake, missed doses and symptoms suggesting intolerance at each visit.

A total of 150 women were included and divided into two equal treatment groups. Group O included 75 women who received ormeloxifene 60 mg orally twice weekly for the first three months, followed by 60 mg once weekly for the next three months. Group TA included 75 women who received tranexamic acid 500 mg orally three times a day during the first three days of menstruation every month for six months. Participants were advised regarding correct drug intake and were followed monthly to assess adherence, symptom status and adverse events.

The primary outcome was reduction in menstrual blood loss, assessed by change in PBAC score from baseline to three and six months. Improvement in haemoglobin was assessed as an additional clinical efficacy outcome because it reflects correction of anaemia associated with reduced bleeding. Safety was assessed through participant-reported adverse events and clinical review during follow-up. The main comparative time points were baseline, three months and six months. Data were summarised as numbers and percentages for categorical variables and mean ± standard deviation for continuous variables. Between-group comparisons for continuous outcomes were interpreted using the available p values. Baseline comparability was assessed before follow-up outcomes were interpreted. A p value below 0.05 was considered statistically significant. Results were presented in consolidated tables to avoid duplication of information and improve readability.

RESULTS

The two treatment groups were comparable at baseline. In the ormeloxifene group, mean age was 30.9 ± 7.9 years; in the tranexamic acid group, mean age was 31.2 ± 7.4 years. The largest age categories were 21-30 years and 31-40 years in both groups. Baseline cycle length was also similar; 40% of women in each group reported a cycle length of 25-28 days. Most women had bleeding for five to six days or seven to eight days, and approximately one-fifth in each group reported bleeding for more than eight days. Duration of symptoms was most often four to five months in the ormeloxifene group and three to five months in the tranexamic acid group.

Heavy and prolonged menstrual bleeding was the commonest bleeding pattern, present in 31 women (41.33%) in each group. Heavy menstrual bleeding alone was reported by 29 women (38.67%) in the ormeloxifene group and 21 women (28%) in the tranexamic acid group. Cyclic and acyclic intermenstrual bleeding patterns were less frequent. In the PALM-COEIN distribution, ovulatory dysfunction was the commonest diagnosis in both groups, followed by endometrial causes and adenomyosis in the ormeloxifene group and leiomyoma and adenomyosis in the tranexamic acid group. Baseline clinical characteristics are combined in Table 1.

Table 1. Baseline Demographic, Menstrual and Diagnostic Characteristics of Study Participants

Characteristic	Ormeloxifene (n = 75)	Tranexamic Acid (n = 75)
Age group (years)		
18-20	5 (6.67)	6 (8.00)
21-30	31 (41.33)	27 (36.00)
31-40	25 (33.33)	30 (40.00)
41-50	14 (18.67)	12 (16.00)
Mean age ± SD	30.9 ± 7.9	31.2 ± 7.4
Menstrual cycle length (days)		
15-17	3 (4.00)	4 (5.33)
18-20	8 (10.67)	7 (9.33)
21-24	20 (26.67)	19 (25.33)
25-28	30 (40.00)	30 (40.00)
29-32	14 (18.67)	15 (20.00)
>33	0 (0.00)	0 (0.00)
Duration of bleeding		
3-4 days	5 (6.67)	4 (5.33)
5-6 days	31 (41.33)	35 (46.67)
7-8 days	23 (30.67)	21 (28.00)
>8 days	16 (21.33)	15 (20.00)
Duration of symptoms		
2-3 months	13 (17.33)	16 (21.33)
3-4 months	17 (22.67)	18 (24.00)
4-5 months	19 (25.33)	18 (24.00)
5-6 months	15 (20.00)	15 (20.00)
6-7 months	11 (14.67)	8 (10.67)
Bleeding pattern		
Heavy menstrual bleeding (HMB)	29 (38.67)	21 (28.00)
Heavy and prolonged menstrual bleeding (HPMB)	31 (41.33)	31 (41.33)
Cyclic midcycle IMB	6 (8.00)	11 (14.67)
Cyclic pre- or postmenstrual IMB	6 (8.00)	6 (8.00)
Acyclic IMB	3 (4.00)	6 (8.00)
PALM-COEIN classification		
Polyp	3 (4.00)	6 (8.00)
Adenomyosis	15 (20.00)	14 (18.67)
Leiomyoma	12 (16.00)	20 (26.67)
Endometrial	16 (21.33)	8 (10.67)
Ovulatory dysfunction	29 (38.67)	27 (36.00)

Values are n (%) unless otherwise stated. IMB: intermenstrual bleeding; SD: standard deviation.

At baseline, mean PBAC score was similar in the ormeloxifene and tranexamic acid groups (155 ± 8.38 vs. 154 ± 9.22; p = 0.380), indicating comparable menstrual blood loss before treatment. At three months, both groups showed reduction in PBAC score, but the reduction was greater with ormeloxifene. Mean PBAC score decreased to 92.6 ± 10.8 in the ormeloxifene group and 104 ± 11.3 in the tranexamic acid group (p < 0.0001). At six months, PBAC score reduced further to 58 ± 12.6 with ormeloxifene and 69.7 ± 12.4 with tranexamic acid (p < 0.0001). The reduction from baseline to six months was 97 points (62.6%) with ormeloxifene and 84.3 points (54.7%) with tranexamic acid.

Haemoglobin improved in both groups. Baseline haemoglobin was 9.32 ± 1.00 g/dL in the ormeloxifene group and 9.12 ± 0.96 g/dL in the tranexamic acid group (p = 0.276). At three months, haemoglobin increased to 10.8 ± 1.09 g/dL and 9.97 ± 1.06 g/dL, respectively (p = 0.008). At six months, mean haemoglobin reached 11.7 ± 1.07 g/dL in the ormeloxifene group and 10.8 ± 1.11 g/dL in the tranexamic acid group (p < 0.001). The PBAC and haemoglobin outcomes are summarised in Table 2, and the trend in PBAC score is shown in Figure 1.

Table 2. Change in PBAC Score and Haemoglobin During Follow-up

Outcome / time point	Ormeloxifene (n = 75) Mean ± SD	Tranexamic acid (n = 75) Mean ± SD	P value
PBAC score			
Baseline	155 ± 8.38	154 ± 9.22	0.380
3 months	92.6 ± 10.8	104 ± 11.3	<0.0001
6 months	58 ± 12.6	69.7 ± 12.4	<0.0001
Haemoglobin (g/dL)			
Baseline	9.32 ± 1.00	9.12 ± 0.96	0.276
3 months	10.8 ± 1.09	9.97 ± 1.06	0.008
6 months	11.7 ± 1.07	10.8 ± 1.11	<0.001

PBAC: Pictorial Blood Assessment Chart; SD: standard deviation.

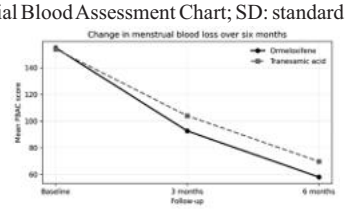

Figure 1. Mean PBAC Score Trend in the Two Treatment Groups
PBAC: Pictorial Blood Assessment Chart.

Anaemia status also improved during follow-up. At baseline, normal haemoglobin values were present in 38.7% of women in the ormeloxifene group and 28% in the tranexamic acid group, while moderate anaemia was present in 32% and 40%, respectively. At three months, 70.7% of women in the ormeloxifene group and 48% in the tranexamic acid group had reached normal haemoglobin values. By six months, normal haemoglobin was documented in 97.3% of the ormeloxifene group compared with 73.3% of the tranexamic acid group. These findings followed the same direction as the mean haemoglobin results.

Both drugs were generally well tolerated. Mild gastrointestinal discomfort and headache were the adverse complaints noted during follow-up. No major adverse event, serious complication or treatment-related hospitalisation was reported in either group during the six-month follow-up period.

DISCUSSION

The present study found that both ormeloxifene and tranexamic acid were effective in women with abnormal uterine bleeding, but ormeloxifene produced a greater reduction in menstrual blood loss and a greater rise in haemoglobin over six months. The groups were similar at baseline for age distribution and major menstrual characteristics, and baseline PBAC and haemoglobin values did not show statistically significant differences. This supports the interpretation that the follow-up differences were related to treatment response rather than marked baseline imbalance. The study population was representative of women commonly seen in outpatient departments, with a mix of heavy bleeding, prolonged bleeding and intermenstrual bleeding. This makes the findings useful for day-to-day decision-making, although individualized evaluation remains essential before starting treatment.

PBAC score was selected as the principal outcome because it provides a practical semi-quantitative assessment of menstrual blood loss and is feasible in outpatient follow-up. The baseline scores in both groups reflected clinically significant heavy bleeding. By three months, PBAC score had fallen substantially in both groups, confirming that each drug had therapeutic benefit. However, the reduction was greater with ormeloxifene at three months and remained greater at six months. The sustained decrease is important because women with AUB often need treatment that not only reduces one menstrual episode but also stabilises bleeding over repeated cycles.

The difference in response may be explained by the different pharmacological actions. Tranexamic acid acts during menstruation by inhibiting fibrinolysis, thereby reducing breakdown of clots and limiting active menstrual blood loss. It is therefore useful for women who prefer medication only during bleeding days and for those in whom hormonal treatment is undesirable. Ormeloxifene, in contrast, modulates estrogen receptor activity and has an anti-estrogenic effect on the endometrium. This may reduce endometrial proliferation and menstrual blood loss across cycles. The weekly maintenance schedule may also improve acceptability for women who prefer intermittent but continuing therapy.

Improvement in haemoglobin is a clinically meaningful endpoint. AUB-related anaemia affects daily performance and contributes to fatigue, weakness and repeated consultation. In this study, haemoglobin increased in both groups, but the gain was greater with ormeloxifene. At six months, the ormeloxifene group improved by approximately 2.38 g/dL from baseline, compared with approximately 1.68 g/dL in the tranexamic acid group. This difference is consistent with the greater reduction in PBAC score and suggests that better control of menstrual blood loss translated into better haematological recovery. The shift in anaemia categories is also important. A higher proportion of women receiving ormeloxifene achieved normal haemoglobin by six months. This outcome is clinically meaningful because correction of anaemia may reduce weakness, improve tolerance to daily activity and decrease the need for more invasive intervention in otherwise stable patients.

The findings are in line with earlier studies. Hymavathi et al. [10] compared ormeloxifene and tranexamic acid in dysfunctional uterine bleeding and observed a significant fall in PBAC score with ormeloxifene, along with improvement in haemoglobin. Kriplani et al. [8] also reported reduction in menstrual blood loss and improvement in haemoglobin among women treated with ormeloxifene for menorrhagia. Evidence for tranexamic acid is also well established; randomized and systematic review data show that it reduces heavy menstrual bleeding, although treatment is limited to bleeding days and does not modify underlying endometrial responsiveness [6,7]. The present study adds local comparative data from a tertiary care teaching institute and supports the usefulness of both medications in routine practice.

The diagnosis distribution in this study is also relevant. Ovulatory dysfunction was the most frequent PALM-COEIN category, which is expected in many outpatient AUB cohorts. Leiomyoma, adenomyosis, endometrial causes and polyps were also represented. This mixed diagnostic profile reflects real-world practice, where women often present with overlapping symptoms and varying structural or non-structural causes. Since marked structural disease may require procedure-based management, medical therapy is best considered in properly selected patients after clinical evaluation. The results should therefore be applied to women similar to the study population and not to those requiring urgent surgical or oncological assessment.

Safety findings were reassuring. Mild gastrointestinal discomfort and headache were observed, but no serious adverse event was recorded. Nevertheless, adverse event interpretation should remain cautious. Tranexamic acid requires care in women with thrombotic risk or contraindications, while ormeloxifene suitability should be individualized after clinical assessment. The absence of serious adverse events in this study supports tolerability over six months but does not exclude rare events. From a counselling perspective, the two drugs can be presented differently. Tranexamic acid is useful for women who want medication only during menses and who have predictable cycles. Ormeloxifene may be more suitable where sustained reduction in bleeding and improvement of anaemia are priorities, provided that the patient accepts the weekly regimen and there are no contraindications.

This study has limitations. It was a single-centre study with six months of follow-up. Blinding was not performed, and formal patient satisfaction or quality-of-life scores were not analysed. Adverse events were recorded clinically but not quantified in detail. The study also did not stratify outcomes by individual PALM-COEIN categories, so treatment response by specific diagnosis could not be assessed. Despite these limitations, the prospective follow-up, objective PBAC and haemoglobin measures and equal group sizes strengthen the practical relevance of the results. Larger multicentre studies with longer follow-up, standardized quality-of-life assessment and diagnosis-wise subgroup analysis would help confirm durability of response and patient acceptability. Future work should also document recurrence after stopping therapy, need for additional medical treatment, progression to procedural management and patient preference regarding dosing schedules. These factors are important because success in AUB management depends not only on reduction in bleeding during treatment, but also on sustained symptom control and acceptability over time.

CONCLUSION

Both ormeloxifene and tranexamic acid were effective in reducing menstrual blood loss and improving haemoglobin levels in women with abnormal uterine bleeding. Ormeloxifene showed superior efficacy at three and six months, with lower PBAC scores and greater haemoglobin improvement. It may be considered a useful non-steroidal option for sustained medical management of AUB, while tranexamic acid remains a valuable cycle-based non-hormonal treatment. Treatment choice should be individualized according to bleeding pattern, anaemia status, contraindications, fertility preference and patient acceptability. The findings support ormeloxifene as an effective option for women who need continuing medical control of AUB, while recognizing that larger studies with longer follow-up are needed to confirm long-term safety, recurrence rates and quality-of-life benefits.

DECLARATIONS

Ethical Approval: Institutional ethical clearance was obtained before recruitment.
Informed Consent: Written informed consent was obtained from all participants.
Conflict of Interest: Nil.
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