

## TO COMPARE THE SUCCESS IN TREATMENT OF DUB WITH ORMELOXIFENE VS NORETHISTERONE

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### Abstract

**Background:** Dysfunctional uterine bleeding occurs when the normal menstrual cycle gets disrupted, and there is prolonged or abnormal uterine bleeding (>80ml per month) in the absence of systemic and genital tract pathology. Progesterone and selective estrogen receptor modulators are used in treating dysfunctional uterine bleeding (DUB). There is a lack of consensus regarding the best agent. The objective of the current study is to compare the success in the treatment of DUB with ormeloxifene vs norethisterone.

**Materials and Methods:** In the present study, patients with dysfunctional uterine bleeding (DUB) presenting to the Department of Obstetrics and Gynaecology at Darbhanga Medical College, Laheriasarai, Bihar, were considered for the study. Enrolment of 100 Perimenopausal women between 40-55 years of age complaining of menorrhagia was taken in this comparative prospective study. They are divided into 2 groups (Group A and Group B). Group A was prescribed Ormeloxifene (60 mg) tablet twice a week for 12 weeks, and group B was given Norethisterone (5 mg) tablet two times a day for 21 days, followed by 7 days withdrawal, for 3 months. Patients were followed up at 3 months. The treatment effectiveness of both the drugs were compared using different parameters like measurement of Pretreatment and post-treatment hemoglobin level, PBAC score and endometrial thickness.

**Result:** In present study both drugs showed an increase in Hb level and significant reduction in blood loss. Ormeloxifene group showed a more significant decrease in endometrial thickness and PBAC score and increase in Hb level which was not significantly reduced in Norethisterone group.

**Conclusion:** On comparing, Ormeloxifene group showed more significant result as compared to Norethisterone.

## INTRODUCTION

Dysfunctional uterine bleeding occurs when the normal menstrual cycle gets disrupted, and there is prolonged or abnormal uterine bleeding (>80ml per month) in the absence of systemic and genital tract pathology.<sup>[1]</sup> When abnormal uterine bleeding (AUB) directly affects the mensuration cycle due to a change in levels of hormone, then the condition is called dysfunctional uterine bleeding (DUB).<sup>[2]</sup> The pathophysiology of DUB is mainly unknown but occurs in both ovulatory and anovulatory menstrual cycles.<sup>[3]</sup> Proper DUB treatment helps prevent heavy blood loss, anaemia and other health complications. Before determining the line of treatment different aspects are considered. There is different method for DUB management, which can be finally personalised to satisfy the desires of patients belonging to different age groups, diverse

socioeconomic background, and of different reproductive needs. Various drugs used in the treatment of DUB are oral contraceptives, progesterone, non-steroidal anti-inflammatory drugs (NSAIDs), different antifibrinolytics such as tranexamic acid, Danazol, GnRH agonists and antagonists (Elagolix), a hemostatic agent such as ethamsylate, Levonorgestrel releasing intrauterine system (LNG IUS). When DUB is not managed by medication, surgical intervention is required.<sup>[4]</sup>

In medical management, two drugs usually prescribed for managing DUB are Ormeloxifene and Norethisterone. Ormeloxifene belongs to third-generation selective estrogen receptor modulators (SERM) which is marketed in India since 1990 as an oral contraceptives (non-steroidal and non-hormonal) and was later introduced as a line of treatment of DUB. It has estrogenic activity in the bone, vagina, blood vascular system, CNS tissues,

and anti-estrogenic activity in the breast and uterus. In women having perimenopausal bleeding with minimal focal pathology, Ormeloxifene treatment was found to be effective and safe.<sup>[5]</sup> It effectively reduces up to 77-85% blood loss with minimal side effects and causes amenorrhea in 17-42% of patients.<sup>[6]</sup> Norethisterone, also known as norethindrone, is artificially synthesized progesterone hormone which imitate the actions of endogenous progesterone.<sup>[7]</sup> Norethisterone is cost effective medicine with no major side effect. So it is often prescribed medication for DUB which serves 38% of the patient population. It suppresses the development of endometrium, reduces menstrual flow, rebuild actual bleeding patterns, and decreases the iron deficiency anaemia cases.<sup>[8]</sup>

In our study, Perimenopausal females between 40-55 years of age presenting with menorrhagia were selected for the study. Patients were divided into two groups with strength of 50 in each. The patient's history regarding menstrual symptoms, family history of diseases, age, and parity were taken and recorded. As DUB is considered as diagnosis of exclusion, different examinations were done to eliminate any additional possible reason for AUB. These comprised of complete blood cell count (CBC), with haemoglobin (Hb) level, coagulation profile, PAP smear, Levels of thyroid stimulating hormone, pelvic ultrasound for ruling out any pelvic pathology, and measuring the endometrial thickness and endometrial sampling. Group A were prescribed drugs Ormeloxifene and Group B were given Norethisterone. Pre and post-treatment hemoglobin levels and endometrial thickness were recorded, and a comparison of the success in treatment with each drug in DUB patients was done.

## MATERIALS AND METHODS

### Study Design

In the present study, patients with dysfunctional uterine bleeding (DUB) presenting to the Department of Obstetrics and Gynaecology at Darbhanga Medical College, Lehriasarai, Bihar, for a time period of 3 months were considered for the study. This was a comparative prospective study in which enrolment of 100 Perimenopausal women between 40-55 years of age complaining with menorrhagia were taken. They are divided in 2 groups (Group A and Group B).

All patients willing to participate gave their informed consent. Their detailed history was taken and clinical examination were conducted.

### Inclusion Criteria

1. Perimenopausal women between 40-55 years of age presenting with menorrhagia attending the Department of Obstetrics and Gynecology, Darbhanga Medical College will be included in the study.

2. Pictorial Blood-Loss Assessment Chart to assess blood loss in menses.
3. All patients are ready for follow-up.

### Exclusion Criteria

1. Patients with pregnancy and lactation, thyroid dysfunction, with the past history of hypertension, polycystic ovarian disease, heart disease, migraine, kidney function and liver impairment will be excluded.
2. Also, patients having adenomyosis, atypical endometrial hyperplasia, fibroid in the uterus and bleeding abnormalities will be excluded.
3. Organic pelvic pathology

DUB is considered as diagnosis of exclusion so examinations were done to exclude any additional probable cause for AUB. DUB diagnosis requires careful exclusion of organic pathology through a detailed history, complete physical examination, and a complete blood count. Pelvic ultrasound is done to measure the thickness of endometrium and to exclude any pelvic pathology and endometrial sampling. The enrolled women were clearly given instructions to keep a menstrual book to note down the total number of days of menses, number of sanitary napkins used, number and size of clots passed, degree of soaking of every napkin, and cases of dysmenorrhoea experienced.

To assess the blood loss in menses, a simple process for objective assessment of menstrual blood loss by PBAC Scoring was done accordingly. The menstrual blood loss  $\geq 80$  ml was given a PBAC score  $\geq 100$  and is considered diagnostic for menorrhagia. PBAC score is measured as shown below in [Table 1].

In the current study ultra-sonographic endometrial thickness was evaluated in all cases before and after treatment.

The women were divided into 2 groups, and each group had 50 cases ready for follow-up. Group A was prescribed Ormeloxifene (60 mg) tablet twice a week for 12 weeks, and group B was given Norethisterone (5 mg) tablet two times a day for 21 days followed by 7 days of withdrawal, for 3 months. Patients were followed up at 3 months.

The primary outcome of the treatment were a reduction in the amount of menstrual blood loss as assessed by fall in PBAC score, rise in hemoglobin level and decrease in endometrial thickness as confirmed by an ultrasound done in proliferative phase.

### Data Analysis

All outcome parameters were represented as Mean and were analyzed using the Z technique. Statistical significance was taken as  $p \leq 0.001$ .

## RESULTS

### Baseline demographics and clinical characteristics

This study was conducted in 100 perimenopausal women between 40-55 years of age having DUB

excluding those with any organic/ systemic/ iatrogenic cause were recruited in this study. Patients were distributed into two group. In Group A Ormeloxifene was prescribed and in group B Norethisterone was prescribed. All the patients were followed up till the end of study.

The distribution of variables among study subjects, including age, parity, and duration of symptoms, is shown in [Table 2]. The average age of patients in Group A was 48 years while in group B was 47.24 years. A majority (96%) of the patients were multiparae. In Group A: 42% patients and in group B : 44 % had 4 or more children. About 70% women has duration of symptom less than 9 month with mean values of 6.22 months.

### Result of investigation prior to treatment

Various results of investigations carried out prior to treatment with the drugs are shown in Table 3. 50% patients in group A and 76% patients in group B has haemoglobin level between 6-8 gm%. The mean Hb level of group A was found to be 7.57 gm% and that of in group B was found to be 6.91gm %. All the patients were categorized on the basis of anaemia according to the National Cancer Institute.9

- Mild: Haemoglobin 10.0 g/dL to lower limit of normal
- Moderate: Haemoglobin 8.0 to 10.0 g/dL
- Severe: Haemoglobin 6.5 to 7.9 g/dL
- Life-threatening: Haemoglobin less than 6.5 g/dL]

Out of total 100 patients, in group A: 38% patients and in group B: 48% patient, were found to have severe anaemia with haemoglobin ranging from 6.5-7.9 g/dl. Life threatening Hb level was found among 18% cases in group A and 40% cases in group B and about 12% in group B were having moderate anaemia. None of the patient has normal level of Hb. Maximum patients had endometrial thickness in the range of 10.1 to 15mm (40 patients in Group A and 33 patients in group B).

### Result of investigation after treatment

The PBAC score assessed among the patients with uterine bleeding shows that maximum patient belongs to intermediate group (201-300). In group A: 72% and in group B: 76% patients has PBAC

score in this range. The mean PBAC score in both group A and B were found to be 274 and 273.

The comparison of post treatment values of mean haemoglobin level, mean PBAC score and mean endometrial thickness between group A (Ormeloxifene) and group B (Norethisterone) is shown in [Table 4] and all these were found to be significant in both the groups (p value <0.001).

### Comparison of data before and after treatment

The comparison data between two groups for haemoglobin level, PBAC score and endometrial thickness and their percentage change before and after treatment is shown in [Figure 1]. The level of haemoglobin significantly increased in the patients after treatment with drugs for 3 months with a percentage change in haemoglobin of 22.73 % in Group A and of 18.53 % in Group B. The PBAC score with percentage change of 67.10% in Group A and 30.40% in Group B was found after treatment with drugs. A decrease in mean endometrial thickness was seen in both group after treatment and a percentage change in endometrial thickness pre and post treatment was found to be 35.63% in Group A and of 11.40% in Group B as shown in [Figure 1].

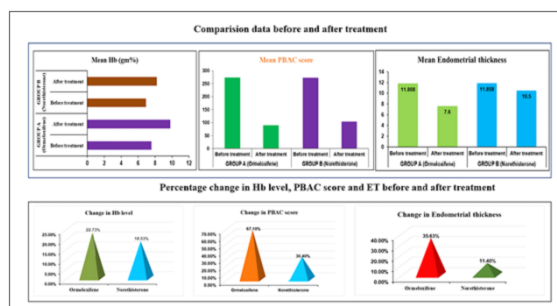


Figure 1: Comparison and percentage change in mean level of Hb, mean PBAC score and mean endometrial thickness

Commonly seen side effects of the both drugs was nausea. In Group A: 38% patient showed side effects out of which 16% had nausea and in Group B: 46% patients experienced side effects out of which 20% had nausea as shown in [Table 5].

Table 1: PBAC scoring

| PADS                                  | SCORES |
|---------------------------------------|--------|
| Lightly soiled pads                   | 1      |
| Moderately soiled pads                | 5      |
| Severely soiled pads                  | 20     |
| CLOTS                                 | SCORES |
| Small clots(less than one rupee coin) | 1      |
| Large clots(more than one rupee coin) | 5      |
| Flooding                              | 5      |

Table 2: Distribution of variables among study subject

| Distribution of variables among study subject |                        |                           |             |                           |             |
|---|------------------------|---------------------------|-------------|---------------------------|-------------|
| Patient Characteristics                       | Ormeloxifene (Group A) |                           |             | Norethisterone (Group B)  |             |
|   |                        | No. of patient N = 50 (%) | Mean values | No. of patient N = 50 (%) | Mean values |
| Age interval (Years)                          | 40-45                  | 19 (38 %)                 | 48          | 19 (38%)                  | 47.24       |
|   | 46-50                  | 13 (26 %)                 |             | 16 (32%)                  |             |

|                                 |       |           |      |           |      |
|---------------------------------|-------|-----------|------|-----------|------|
|                                 | 51-55 | 18 (36 %) |      | 14 (28%)  |      |
|                                 | >55   | 0         |      | 1 (2%)    |      |
| Parity status                   | 01    | 0         | 3.64 | 4 (8%)    | 3.53 |
|                                 | 02    | 13 (26%)  |      | 12 (24%)  |      |
|                                 | 03    | 16 (32%)  |      | 12 (24%)  |      |
|                                 | ≥04   | 21 (42%)  |      | 22 (44 %) |      |
| Duration of symptoms (in month) | 0-3   | 18 (36%)  | 6.1  | 17 (34%)  | 6.22 |
|                                 | 4-6   | 10 (20 %) |      | 10 (20%)  |      |
|                                 | 7-9   | 10 (20%)  |      | 10 (20%)  |      |
|                                 | 10-12 | 11 (22%)  |      | 12 (24%)  |      |
|                                 | >12   | 1 (2%)    |      | 1 (2%)    |      |

**Table 3: Result of various investigations prior to the treatment**

| Result of investigation before treatment |         |                   |         |                   |         |
|--|---------|-------------------|---------|-------------------|---------|
| Investigation                            |         | Group A N= 50 (%) | Mean Hb | Group B N =50 (%) | Mean Hb |
| Haemoglobin level (gm %)                 | <6      | 3 (6%)            | 7.572   | 6 (12%)           | 6.918   |
|  | 6-8     | 25 (50%)          |         | 38 (76%)          |         |
|  | 8.1-10  | 22 (44%)          |         | 6 (12%)           |         |
| Endometrial thickness (mm)               | 0-5     | 0                 | 11.808  | 0                 | 11.858  |
|  | 5.1-10  | 8 (16%)           |         | 8 (16%)           |         |
|  | 10.1-15 | 40 (80%)          |         | 33 (66%)          |         |
|  | 15.1-20 | 2 (4%)            |         | 9 (18%)           |         |
| PBAC score                               | 100-200 | 0                 | 274     | 0                 | 273     |
|  | 201-300 | 36 (72%)          |         | 38 (76%)          |         |
|  | 301-400 | 14 (28%)          |         | 12 (24%)          |         |

**Table 4: Role of ormeloxifen and Norethisterone on rise of haemoglobin, endometrial thickness, and improvement in PBAC score after three month of treatment.**

| Outcome parameters           | Ormeloxifene | Norethisterone | p-value |
|------------------------------|--------------|----------------|---------|
| Mean Hemoglobin level (gm %) | 9.8          | 8.2            | <0.001  |
| Mean PBAC score              | 90           | 190            | <0.001  |
| Endometrial thickness (mm)   | 7.6          | 10.5           | <0.001  |

**Table 5: Side effect of treatment**

| Side Effects    | Group A (Ormeloxifene) | Group B (Norethisterone) |
|-----------------|------------------------|--------------------------|
| Nausea          | 8 (16%)                | 10 (20%)                 |
| Headache        | 5 (10%)                | 6 (12%)                  |
| White Discharge | 6 (12%)                | 3 (6%)                   |
| Spotting        | -                      | 4 (10%)                  |
| Total           | 19 (38%)               | 46 (50%)                 |

Side effects are considerably more in Group B as compared to group A. On comparing both the drugs by their market price it was found that ormeloxifene is more cost effective than Norethisterone. The cost of one tablet of ormeloxifene (Drug A) is Rs.9 so the total cost of 3 months of treatment with Drug A would be Rs.216. The cost of norethisterone (Drug B) is Rs.4 and total cost of treatment would be Rs.504, which is almost double that of Drug A.

## DISCUSSION

The commonest condition which affects the quality of women's life is DUB and there is urgent need for treating women with such condition.

Both medical and surgical means of management have been practiced like.

1. Medical management with contraceptive pills, NSAIDs, progestones and antifibrinolytics.
  2. Levonorgestrel releasing intra uterine device
  3. Surgery ,hysterectomy and Endometrial ablation.
- Medical management has always been the first choice for management of DUB and if it fails to show desired results then surgical interventions are

needed. Hysterectomy should be the last alternative in the management of DUB.

Different studies reported in literatue showed that Ormeloxifene is a designer drug and is more effective in the treatment of DUB at any age.<sup>[10]</sup> It is an optimally designed selective estrogen receptor modulators (SERM) and acts on the estrogen receptor with diverse tissue response. It also relieves premenstrual syndrome in peri-menopausal women. Ormeloxifene is very effective in improving all the parameters of blood loss including the number of days of bleeding, number of pads soiled and passage of clots. It regularises the bleeding from uterine cavity by normalising the expression of ER on endometrium and hence the drug was tested in patients with DUB. It is also an effective anti-proliferative agent in breast tissue. An additional benefit of this drug is that it reduces total cholesterol, LDL cholesterol by about 20 to 30%.<sup>[11]</sup> Conventionally the dosage used for the treatment of DUB which is presently, AUB-O,E was 60mg twice weekly for 12 weeks followed by 60mg once weekly for 12 weeks.<sup>[12]</sup> Our study was conducted for three month and prescribed dose was 60mg twice weekly for 12 weeks.

Norethisterone (Primolut-N) is a synthetic hormone and first generation progesterone with androgenic effects that works by imitating the activity of the natural progesterone hormone. It re-establishes hormone levels in the body and controls the development and shedding of the uterine lining. Thus, it helps to treat menstrual disorders. It is used to treat painful, heavy, and irregular periods, premenstrual syndrome (PMS), and endometriosis. In some cases, side effect of Norethisterone is abnormal vaginal bleeding or spotting, dry mouth, dizziness, nausea, diarrhoea, constipation, headache, breast pain, and tenderness. Most of these side effects do not require medical urgency and gradually resolve over time. Many studies reported in literature showed the effectiveness of norethisterone in treatment of DUB.<sup>[13]</sup> Progestogens are good choice in patients with anovulatory bleeding. It induces endometrial maturation and reverse the effects of estrogen facilitated endometrial proliferation. In a study it was found that Norethisterone arrest bleeding in patients with DUB having menorrhagia but it had additional side effects and after stopping the drug, bleeding recurred.<sup>[14]</sup>

In the present study, the efficacy and safety of Ormeloxifene was compared with Norethisterone which was done prospectively. The mean age of the patients in Group A was 48 years and 47.24 years in Group B. This study group is in accordance with previous studies.<sup>[15,16]</sup> Most of the patients were multiparae, which was also seen in the previous studies.<sup>[17]</sup>

Fewer side effects were reported in both the treatment groups which did not cause any failure of patient compliance. Ormeloxifene is cheap drug and cost effective as compared with Norethisterone. In present study both drug showed an increase in Hb level and significant reduction in blood loss. On comparing, Ormeloxifene group showed more significant result as compared to Norethisterone. Ormeloxifene group showed significant decrease in endometrial thickness, which was not significantly reduced in Norethisterone group. In present study Ormeloxifene found more effective in treatment of DUB than Norethisterone in term of better tolerance, patient compliance, cost effectiveness and suitable dosage schedule. Hence our study concludes Ormeloxifene as better choice over Norethisterone in treatment of DUB.

## CONCLUSION

Our study and literature shows Ormeloxifene as a designer drug in treating DUB. An uncomplicated and straightforward tool for assessing of menstrual blood loss is PBAC score. It has several advantage such as cost effective method, no special equipment or set up is required, less time taking method, women having normal blood flow can be easily differentiated from those having HMB. The amount of bleeding can be easily measured, compared and

recorded during each cycle. It is also used to understand the efficacy of the treatment in patients of AUB. Our study observed following results:

1. Ormeloxifene can reduce the menstrual blood loss significantly to less than 80ml which cause symptomatic relief of HMB compared to Norethisterone by the end of 3 months usage. At the end of 3 months, there was a 67.10 % reduction in Ormeloxifene as compared to Norethisterone group with 30.40%.
2. Patients belonging to perimenopausal age group will get benefit from Ormeloxifene as they transit to menopause.
3. Decrease in PBAC and increase in haemoglobin levels with both the drugs is significant in the study, Ormeloxifene showed better results.
4. Ormeloxifene has several advantage over Norethisterone as it showed better drug compliance, easily affordable, low cost treatment, better patient satisfaction, no severe adverse effect needing urgent intervention, along with a good safety margin, shows the wide acceptability of this drug.

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### Declaration of Conflicting Interests

The Authors declare that there is no conflict of interest.

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