ORIGINAL RESEARCH

Effective Role of Ormeloxifene in Management of Dysfunctional Uterine Bleeding in Perimenopausal Age Group

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ABSTRACT

Background: Dysfunctional uterine bleeding (DUB) is abnormal genital tract bleeding based in the uterus and found in the absence of demonstrable structural or organic pathology. The present study was conducted to assess utility of Ormeloxifene in management of dysfunctional uterine bleeding in perimenopausal women.

Materials & Methods: 80 women age range 40-50 years with dysfunctional uterine bleeding, who attended to out-patient department of Obstetrics & Gynaecology of Nalanda Medical College & Hospital, Patna Bihar, India were treated with Ormeloxifene tablet 60 mg, twice a week. The patients were followed-up at 4th, 8th ,12th and 25th week of treatment. Pictorial blood loss assessment chart (PABC) was used to measure the menstrual blood loss.

Results: Symptoms were polymenorrhoea in 8, Menorrhagia in 32, Polymenorrhagia in 20, Peri menopausal bleeding in 7, Intermenstrual spotting in 6, Metropathia Haemorrhagica in 7. Marital status was 15 married and 65 unmarried. Parity was multipara in 71 and nullipara in 9. The difference was significant (P< 0.05). At baseline mean PABC score was 258.4 and at post- treatment was 102.6. At baseline, mean endometrial thickness was 11.3 and at post- treatment was 9.4. The mean hemoglobin level at baseline was 9.1 gm/dl and at post- treatment was 10.2 gm/dl. At baseline, 62 patients showed presence of clots which decreased to 14 at post- treatment. The difference was significant (P< 0.05).

Conclusion: Ormeloxifene proved to be effective in decreasing menstrual blood loss among patients suffering from DUB. It was determined to be an excellent medication for managing the systems of dysfunctional uterine bleeding without affecting normal endocrinal and physiological parameters.

Keywords: Dysfunctional uterine bleeding, Ormeloxifene, Polymenorrhoea

INTRODUCTION

Dysfunctional uterine bleeding (DUB) is abnormal genital tract bleeding based in the uterus and found in the absence of demonstrable structural or organic pathology. DUB can arise from altered hypothalamic-pituitary-ovarian function and/or local changes in PG production.[1] It is usually marked by a significant, extended flow, which may or may not include breakthrough bleeding. DUB is a diagnosis that encompasses not only menorrhagia but also excessively prolonged and frequent bleeding, known as menometrorrhagia. Its occurrence is more common in anovulatory cycles than in ovulatory ones.[2] Dysfunctional uterine bleeding, affecting women of all ages, is a prevalent and

debilitating issue that constitutes 20% of visits to gynaecological practices. Despite the current development of minimally invasive surgical approaches, traditional hysterectomy remains the only suitable definitive treatment for those who do not wish to conceive further.[3]

Although various treatment options exist, an effective drug for managing dysfunctional uterine bleeding should fulfill criteria such as effectiveness, ease of use, affordability, minimal side effects, and a long safety margin. Selective estrogen receptor modulator drugs (SERM), commonly referred to as Designer estrogens or Fantasy estrogens, selectively bind with high affinity to estrogen receptors, mimicking the effects of estrogen in some tissues while acting as antagonists in others.[4]

Ormeloxifene (centchroman) is a member of the selective estrogen receptor modulators, or SERMs, which are medications that target the estrogen receptor. This is a non-steroidal and non-hormonal oral contraceptive that is taken weekly. Ormeloxifene has been marketed as a contraceptive in India since the early 1990s.[5] It exerts its effects through a high-affinity interaction with the estrogen receptor (ER), counteracting the influence of estrogen on breast and uterine tissue while stimulating effects in the vagina, bone, cardiovascular system, and central nervous system.[6]

AIM AND OBJECTIVES

Aim

To assess the efficacy of ormeloxifene in the medical management of dysfunctional uterine bleeding in perimenopausal women aged 40–50 years.

Objectives

1. Evaluate the reduction in menstrual blood loss using the Pictorial Blood Loss Assessment Chart (PBAC) score before and after ormeloxifene treatment.
2. Measure changes in endometrial thickness via transvaginal ultrasonography pre- and post-treatment.
3. Assess improvements in hemoglobin levels to determine the impact on anemia associated with DUB.
4. Monitor the presence of blood clots during menstruation as an indicator of bleeding severity.
5. Determine the overall effectiveness and safety of ormeloxifene as a non-surgical treatment option for DUB in the specified demographic.

MATERIALS AND METHODS

Study Design

This was a prospective interventional study conducted to evaluate the effectiveness of Ormeloxifene in the management of dysfunctional uterine bleeding (DUB) among perimenopausal women.

Study Population

The study involved 80 perimenopausal women aged between 40 and 50 years presenting with symptoms of dysfunctional uterine bleeding. These women attended the Outpatient Department, Department of Obstetrics and Gynecology, Nalanda Medical College & Hospital, Patna, Bihar, India.

Study Place

The study was conducted in the Department of Obstetrics and Gynecology, Nalanda Medical College and Hospital, Patna, Bihar, India.

Study Duration

The study was carried out over a period of 12 months, from March 2017 to February 2018, allowing for recruitment, examination, and analysis. The study included initial recruitment and follow-up visits at 4th, 8th, 12th, and 25th weeks post-treatment initiation.

Inclusion Criteria

- Women aged 40–50 years
- Diagnosed clinically with dysfunctional uterine bleeding
- Regular follow-up feasible for 25 weeks
- Willing to participate with informed written consent

Exclusion Criteria

- Known or suspected malignancy
- Pelvic inflammatory disease, uterine fibroids, or adenomyosis confirmed on ultrasound
- Coagulopathies, liver dysfunction, or systemic diseases
- Hormonal treatment taken within last 3 months
- Pregnancy or lactation

Ethical Considerations

- All participants provided written informed consent before enrollment.
- Ethical clearance was assumed to be obtained from the Institutional Ethics Committee of Nalanda Medical College & Hospital, in accordance with the Declaration of Helsinki.

Study Procedure

1. Baseline Evaluation:

Demographics, medical history, and clinical examination findings were documented.

Investigations included:

Complete Blood Count (CBC)
Clotting Time (CT) and Bleeding Time (BT)
Thyroid function tests
Liver function tests
Ultrasound abdomen and pelvis (to rule out structural causes)
Endometrial histopathology (to exclude malignancy/hyperplasia)

2. Treatment Protocol:

All eligible patients received Ormeloxifene 60 mg tablets, administered twice weekly.

3. Follow-up Schedule:

Clinical evaluation and symptom review at 4th, 8th, 12th, and 25th weeks
Pictorial Blood Loss Assessment Chart (PBAC) used at each visit to quantify menstrual blood loss.
Endometrial thickness measured during premenstrual phase at baseline and at the 25th week via transabdominal ultrasonography.

4. Classification of Dysmenorrhea:

Graded as: absent, mild, moderate, or severe based on patient self-reporting.

RESULTS

Outcome Measures

1. Primary Outcome:

Reduction in menstrual blood loss, assessed via PBAC score
A PBAC score ≥100 was indicative of menorrhagia (blood loss ≥80 mL)

2. Secondary Outcomes:

Change in endometrial thickness
Change in severity of dysmenorrhea
Patient-reported symptom improvement

Statistical Analysis

Data were entered in a spreadsheet and analyzed using Microsoft excel and IBM SPSS software Version 20.0.
Descriptive statistics (mean, SD) and inferential statistics (e.g., paired t-tests, Chi-square tests) were used.
A p-value < 0.05 was considered statistically significant.

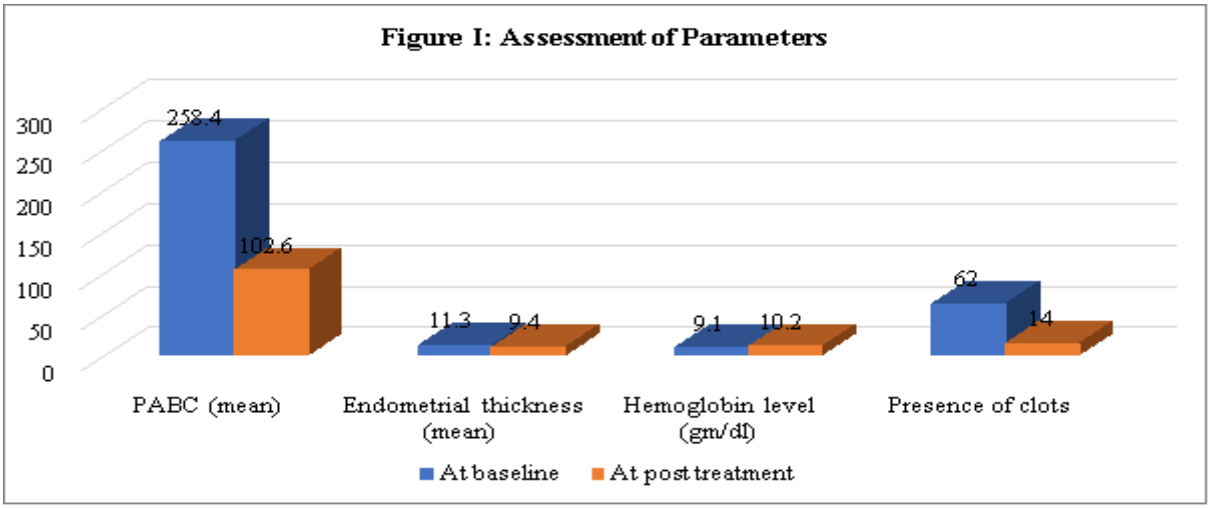
Table 1: Demographic Characteristics of the Participants

Parameters	Variables	Number	P value
Symptoms	Polymenorrhoea	8	0.05
	Menorrhagia	32	
	Polymenorrhagia	20	
	Peri menopausal bleeding	7	
	Intermenstrual spotting	6	
	Metropathia Haemorrhagica	7	
Marital status	Married	15	0.02
	Unmarried	65	
Parity	Multipara	71	0.01
	Nullipara	9	

Table 1 shows that symptoms were polymenorrhoea in 8, Menorrhagia in 32, Polymenorrhagia in 20, Peri menopausal bleeding in 7, Intermenstrual spotting in 6, Metropathia Haemorrhagica in 7. Marital status was 15 married and 65 unmarried. Parity was multipara in 71 and nullipara in 9. The difference was significant (P< 0.05).

Table 2: Assessment of Parameters

Parameters	At baseline	At post treatment	P value
PABC (mean)	258.4± 86.25	102.6 ± 72.50	0.01
Endometrial thickness (mean)	11.3± 1.2 mm	9.4± 1.3 mm	0.05
Hemoglobin level (gm/dl)	9.1± 1.3 g/dL	10.2± 1.5 g/dL	0.05
Presence of clots	62	14	0.01



PBAC = Pictorial Blood Loss Assessment Chart.

Table 2, figure I shows that at baseline mean PABC score was 258.4 and at post- treatment was 102.6. At baseline, mean endometrial thickness was 11.3 and at post- treatment was 9.4. The mean hemoglobin level at baseline was 9.1 gm/dl and at post- treatment was 10.2 gm/dl. At baseline, 62 patients showed presence of clots which decreased to 14 at post- treatment. The difference was significant (P< 0.05).

DISCUSSION

Ormeloxifene effects are mediated through a high-affinity interaction with the estrogen receptor (ER), countering estrogen's impact on breast and uterine tissue while promoting its effects on the vagina, bone, cardiovascular system, and central nervous system.[7] Ormeloxifene is not only favoured as an oral contraceptive, but it is also effective in treating dysfunctional uterine bleeding and advanced breast cancer.[8] For the pharmacological management of DUB, the standard treatment involves an oral dosage of 60 mg twice a week for 12 weeks, followed by a weekly dosage for the next 12 weeks.[9,10] Ormeloxifene has an excellent safety profile, with only a few side effects such as nausea, headaches, weight gain, and delayed or prolonged menstrual periods.[11] The present study was conducted to assess utility of Ormeloxifene in management of dysfunctional uterine bleeding in perimenopausal women.

We found that symptoms were polymenorrhoea in 8, Menorrhagia in 32, Polymenorrhagia in 20, Peri menopausal bleeding in 7, Intermenstrual spotting in 6, Metropathia Haemorrhagica in 7. Marital status was 15 married and 65 unmarried. Parity was multipara in 71 and nullipara in 9. Ravibabu K et al[12] in their study found 10 (20%) unmarried and 40 (80%) married. Parity was multipara in 35 (87.5%) and nullipara in 5 (12.5%).

We observed that at baseline mean PABC score was 258.4 and at post- treatment was 102.6. At baseline, mean endometrial thickness was 11.3 and at post- treatment was 9.4. The mean hemoglobin level at baseline was 9.1 gm/dl and at post- treatment was 10.2 gm/dl. At baseline, 62 patients showed presence of clots which decreased to 14 at post- treatment. We found significant reduction in PABC score and endometrial thickness following treatment with Ormeloxifene. There was improvement in hemoglobin level of patient post- treatment. Similar results were obtained by Ravibabu K et al[12] who evaluated the efficacy of Ormeloxifene in the pharmacological management of dysfunctional uterine bleeding. 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). There was also significant decrease in the mean endometrial thickness (p<0.001) after treatment with Ormeloxifene when compared to mean baseline value. The difference in mean haemoglobin level is 1.3 gm/dl between baseline and post treatment levels and was found to be statistically significant (p<0.001). There was significant improvement, 84% of patients had relief from dysmenorrhoea (p<0.001).

Biswas SC et al[13] evaluated the efficacy of Ormeloxifene for dysfunctional menorrhagia (DUB) in 85 women aged 30 to 51 years and found that the median difference between pretreatment and post-treatment PBAC score of

97.2 was statistically significant (P<0.01). The difference in mean hemoglobin concentration of 1.31 gm/dl between pretreatment and post-treatment levels was also statistically significant (P<0.01, 95% CI= 0.389 to 2.23). Seventy four out of 85 subjects (87.05%) showed a reduction in endometrial thickness as assessed by transvaginal sonography (TVS). Out of 85 (8.2%) women needed hysterectomy.

LIMITATIONS OF THE STUDY

- Sample Size was relatively small (n=80), limiting the generalizability of results.
- Single-centre study may introduce institutional bias.
- Lack of control group—no comparison with other treatment modalities like hormonal therapy or surgical intervention.
- Short follow-up duration of 25 weeks may not capture long-term efficacy or recurrence.
- Self-reported PBAC scores might introduce subjectivity and variability.
- Use of transabdominal ultrasound rather than transvaginal may have reduced precision in endometrial thickness measurements.

CONCLUSION

Authors found that Ormeloxifene proved to be effective in decreasing menstrual blood loss among patients suffering from DUB. It was determined to be an excellent medication for managing the systems of dysfunctional uterine bleeding without affecting normal endocrinal and physiological parameters. Ormeloxifene is an effective and safe non-surgical treatment option for managing DUB in perimenopausal women, offering significant improvements in menstrual blood loss, endometrial thickness, and hemoglobin levels.

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