

TO OBSERVE EFFECT OF ORMILOXIFENE IN MEDICAL MANAGEMENT OF DYSFUNCTIONAL UTERINE BLEEDING

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HOW TO CITE THIS ARTICLE:

Deepa Masand, Sweta Gupta, Jaya Patel "To Observe Effect of Ormioxifene in Medical Management of Dysfunctional Uterine Bleeding". Journal of Evolution of Medical and Dental Sciences 2015; Vol. 4, Issue 04, January 12; Page: 587-597, DOI: 10.14260/jemds/2015/87

ABSTRACT: OBJECTIVE: To evaluate the efficacy and safety of ormeloxifene in the medical management of dysfunctional uterine bleeding. **DESIGN AND SETTING:** A descriptive observational study was conducted on women with dysfunctional uterine bleeding, who attended to out – patient department of Obstetrics & Gynaecology in a National Institute Of Medical Science Medical College, shobha nagar, Jaipur (Rajsthan). **MATERIAL AND METHOD:** 54 patients with dysfunctional uterine bleeding were recruited for the study. Ormeloxifene 60 mg twice a week for 3 months from first day of periods and once a week for next 3 months was given. Mean blood loss (MBL) was assessed using pictorial blood loss assessment chart (PBAC). And subjectively by a visual analog scale (VAS). Ultrasonography (USG) for endometrial thickness and blood hemoglobin levels were done as baseline and at 1, 3 and 6 months of treatment. Side-effects of the drug were recorded. Changes in PBAC scoring, endometrial thickness (ET) and hemoglobin levels (Hb) were analyzed by student's paired 't' tests using SPSS 17.0 version. p value ≤ 0.05 was taken as significant. **RESULT:** The mean pretreatment 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 < 0.001). Out of 54 patients, 46 women with menorrhagia were recruited in study. Three (6.52%) patients had no response, four (8.7%) patients were lost to follow-up. During the one year study period, 1 (2.17) of the patients underwent hysterectomy. The most common side effect reported was amenorrhea (28.26%). **CONCLUSION:** Ormeloxifene is very effective in improving all the parameters of blood loss in abnormal uterine bleeding including the no. of days of bleeding, no. of pads soiled and the passage of clots. Ormeloxifene has a good patient acceptability and compliance due to its minimal side effects, low cost and simple dosage schedule.

KEYWORDS: Dysfunctional uterine bleeding, menorrhagia, ormeloxifene, hysterectomy.

INTRODUCTION: Menorrhagia is defined as cyclical bleeding at normal intervals which is excessive in amount (total blood loss greater than 80 ml) or duration (lasting longer than 7 days). or a pictorial blood loss assessment chart score of more than 100.¹

Abnormal uterine bleeding is defined as any bleeding that does not correspond with the frequency, duration or amount of blood flow of normal menstrual cycle.²

Annually 5-10% of woman of reproductive age seek medical care for AUB. Which negatively impacts quality of life.³

Abnormal uterine bleeding in reproductive age women is common, leading to one third of outpatient visits by this population and this proportion crosses the two third threshold in peri or

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post-menopausal group 3 over all it account for 6.2% of genitourinary disease reporting to outpatient department and may account for more than 25% of all hysterectomies.^{4,5}

Altered hypothalamic – pituitary- ovarian function and /or local changes in prostaglandine production can give rise to DUB. It is typically characterized by heavy, prolonged flow with or without breakthrough bleeding. It occurs more frequently in anovulatory than ovulatory cycles.⁶

A wide range of treatment modalities are available which include medical therapy and surgical interventions. Pharmacological management can be hormonal or non-hormonal. Hormonal agents include oestrogens, progesterones, combination of the two, androgens, danazol, GnRH agonists and the latest SERMS (Selective Oestrogen Receptor Modulators). Non-hormonal drugs like NSAIDs, ethamsylate and anti-fibrinolytics have also been found to be highly effective. Medical management has always been the first therapeutic option to be tried and if it fails to show results, one can resort to surgical interventions. Hysterectomy should be the last resort in the management of DUB. Because of the morbidity associated with the surgical procedures, the RCOG recommends beginning with medical management before resorting to surgical interventions.⁷ Medical treatment of menorrhagia should aim to relieve symptoms, improve quality of life and avoid the risk of surgery.

Ormeloxifene is a benzopyran SERM, which blocks the cytosol receptors by its competitive binding over estradiol. It has mild estrogenic activity on vagina, bone mineral density, CNS and lipids.⁸

The drug is primarily a potent estrogen antagonist but also has a weak agonist activity in selected tissues. The drug demonstrates a suppressive or a stimulatory effect on gonadotropin release. Such antiestrogens are expected to exert contraceptive effects. It normalizes the bleeding from uterine cavity by regularizing the expression of estrogen receptors on the endometrium and, hence the drug was tried in patients of DUB. It is also a potent antiproliferative agent in breast tissue. Chronic use upto 4 years has shown no evidence of common, serious adverse events and no serious ovarian pathology.

Additional benefit of this drug is that it decreases total cholesterol, LDL cholesterol by about 20 to 30%. The drug is known to increase ET significantly without proliferation.⁹

TYPES OF SERMS:

I generation: Tripbenylethylene derivative- Tamoxifene, Droloxifene, Toremifene.

II generation: Benzothiophene derivative- Raloxifene.

III generation: Ormeloxifene, Ospernifene, Arzoxipene, Lasoxifene.

CHEMISTRY OF ORMELOXIFENE: The chemical name of ormeloxifene is Trans-7-methoxy-2, 2-dimethyl-3 -phenyl- 4(4-(2-pyrrolidinoethoxy) phenyl (- chromanhydrochloride).¹⁰

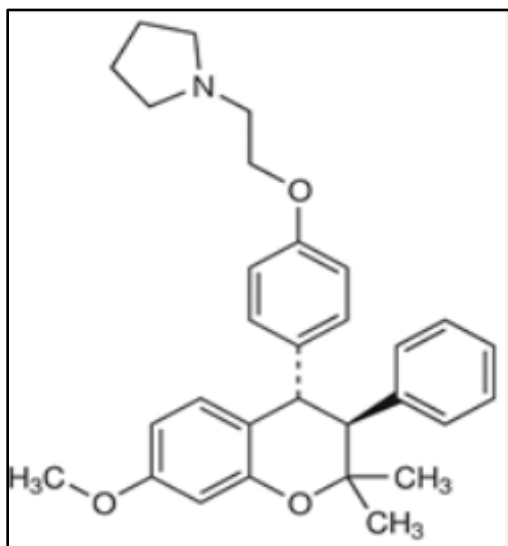


Fig. 1: Ormeloxifene molecule

MATERIAL AND METHODS: The descriptive observational study was conducted in the department of Obstetrics and Gynaecology at National institute of medical sciences & hospital, Jaipur (Rajasthan), during the period of November 2012 to March 2014.

SELECTION CRITERIA: 54 women of reproductive age group who attended the OPD of Department of obstetrics & gynaecology with complaint of heavy menstrual flow were recruited for the study of which 46 came for regular follow up for 6 months of treatment and later also.

EXCLUSION CRITERIA: Patient with known pelvic pathologies like uterine fibroid, endometriosis, malignancies of genital tract, medical disease like liver dysfunction, heart disease, coagulopathies, renal disease, pregnancy, IUCD or pill users, lactating women in the first 6 months of postnatal period, thyroid disorder, history of abortion within last 3 months and hypersensitivity to drug. Those with heavy bleeding necessitating emergency treatment, and those who were on estrogen, progesterone, testosterone or danazol, prostaglandin synthetase inhibitors, antifibrinolytic therapy were excluded from the study.

Subjects were selected at random from outpatient Department of Obstetrics and Gynaecology after informed consent. Detailed menstrual history was taken. General examination was done to assess the anaemia, obesity and to rule out any signs and symptoms of bleeding disorders, hypothyroidism and jaundice. A pelvic examination was done to rule out pregnancy, fibroid, adenomyosis or any other pathology. Baseline investigations were conducted for hemoglobin levels. TLC, DLC, bleeding time, clotting time, platelet count, prothrombin time and peripheral smear for cell morphology were done to rule out bleeding dyscrasias. TSH levels were advised to rule out occult hypothyroidism.

Pap smears were taken and endometrial biopsy was taken. The drug was administered orally in the form of 60 mg tablet twice weekly for the first 12 weeks and then once a week for another 12

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weeks. Patients were told to keep a record of their menstrual blood loss including the interval at which the menses were coming, number of days of bleeding, number of pads soiled and degree of soiling, history of passage of clots and dysmenorrhoea. Patients were asked to come for regular follow up every 30 days. On each follow up, they were asked about the blood loss and any other complaints. Hemoglobin estimation was done. A TVS was done for endometrial thickness and any other pathology. Two pre-treatment baseline cycles were compared to the treatment cycles of ormeloxifene. The main outcomes measured were menstrual blood, blood haemoglobin levels and endometrial thickness in proliferative phase as studied by TVS.

Pictorial blood loss assessment chart (PBAC) was used to measure the menstrual blood loss (MBL). The women were asked to use certain sanitary napkins which have similar absorbent capacities. They recorded the number of napkins used each day and the degree of soiling of each pad used. Number and sizes of clots passed were also noted. Scores were assigned to different degrees of soiling of sanitary napkins and number and size of clots passed. A PBAC score of greater than or equal to 100 was considered diagnostic of menorrhagia. The main outcome measures were MBL, passage of clots, blood hemoglobin (Hb) level and ET in proliferative phase by TVS.

RESULTS:

	N	Mean	Std. Deviation	Median	Minimum	Maximum
Age	46	36.72	7.36	36	21	53
Duration of Menorrhagia(months)	46	12.77	10.20	9.5	4	40
Duration of Bleeding(days)	46	7.57	5.63	6	4	30
Cycle Length	46	18.83	3.92	18.5	11	25

Table 1: Patient Profiles

Table-1 shows the mean age of the study population was 36.72 (21-53). Majority (82.61) of the women were multiparous,. The median duration of menorrhagia was 12.77 months (4-40 months). The median duration of bleeding days was 7.57 days (4-30) and median cycle length was 18.83 days (11-25).

Marital Status	No.	%
Married	44	95.65
Unmarried	2	4.35
Parity		
Multipara	38	82.61
Nulli para	8	17.39

Table 2: Demographic Characteristics of study group (N=46)

Table-2: depicts the demographic data of the patients in the study. Bleeding was more common in multipara. This may be due to altered pituitary ovarian function following delivery.

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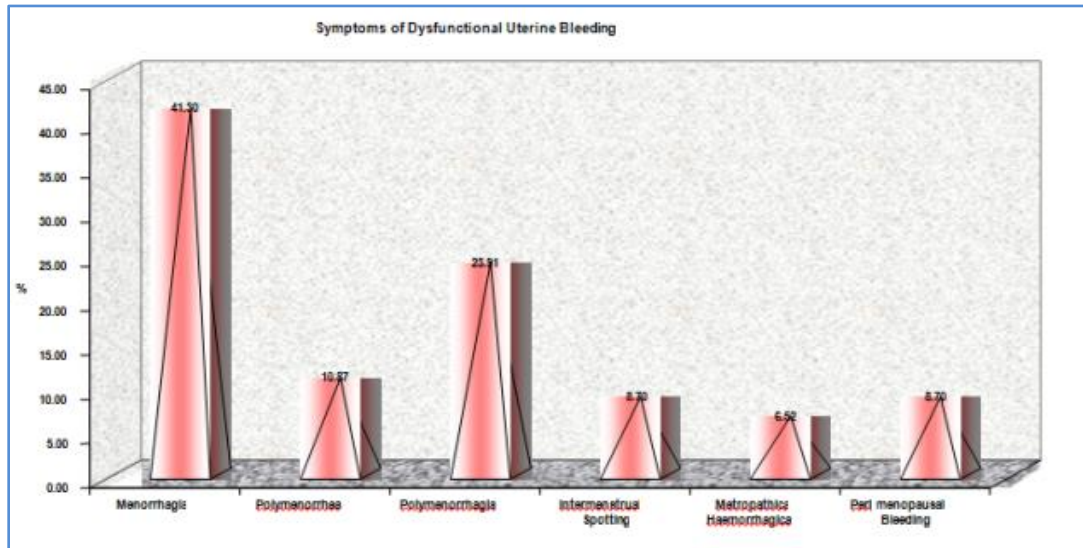


Fig. 2: symptoms of dysfunction uterine bleeding before treatment

Menstrual Pattern	No.	%
Regular menses	29	63.04
Amenorrhoea	13	28.26
Scanty menses	4	8.70
Total	46	100.00

Table 3: Follow-up at 6 months after completing treatment

The Table 3- shows that 63.04% of patients has regular normal menses at 6 months follow up. 28.26% has amenorrhoea and 8.7% were having regular scanty menses.

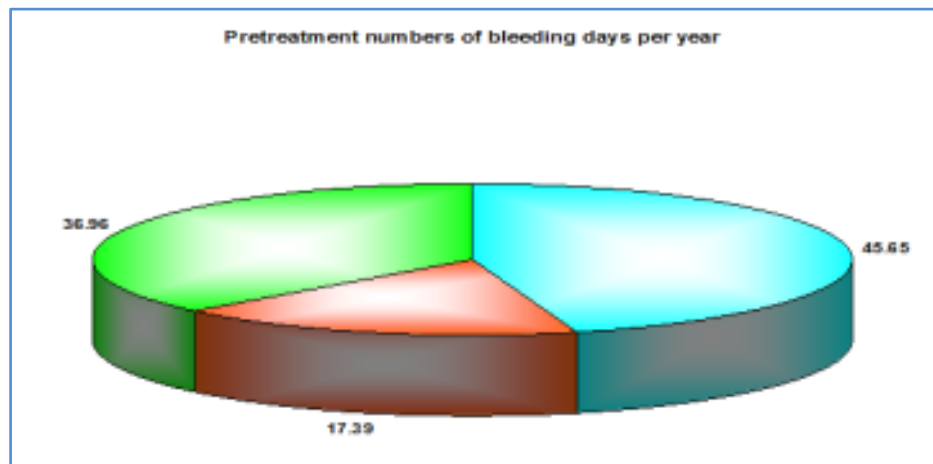


Fig. 3

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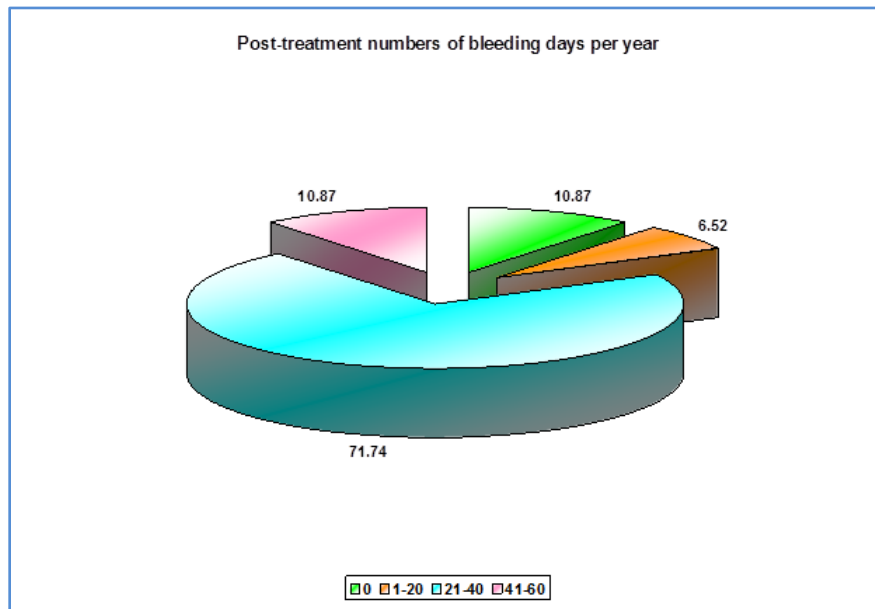


Fig. 4

Figure 3 & 4 shows -Total of bleeding days per year decreased by 76% with the treatment. Maximum decrease was seen in patients with more pre-treatment bleeding days.

Dysmenorrhoea	No.	%
Persisted	12	26.09
Decreased	16	34.78
Disappeared	18	39.13

Table 4: Dysmenorrhoea (N=46)

Table-4 shows Dysmenorrhoea was relieved in 73.91% patients who initially has this complain.

N=46	Pretreatment	Post-treatment (1 st month)	Post-treatment (3 rd month)	Post-treatment (6 th month)	Remarks *
Mean PBAC (ml)	140-765 (Mean-343.13)	80-398 (Mean-222.22)	0-340 (Mean-90.0)	0-320 (Mean-68.84)	P<0.001
Mean Hb (g/dl)	9.08±1.15 (6.7-11.1)	10.19±1.11 (7.6-12.5)	10.73±1.04 (8.6-12.9)	-	P<0.001
Mean ET (mm)	8.55±2.42 (3.49-14.93)	7.57±2.76 (2.2-14.42)	5.91±1.65 (2.46-10.18)	5.41±1.78 (0.29-8.68)	P<0.001

Table 5: Outcome measurements of PBAC, Mean Hemoglobin and Endometrial Thickness.

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TABLE 5 SHOWS:

RESPONSE ON DURATION OF BLEEDING AND MESTRUAL BLOOD LOSS: The mean pretreatment 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 \leq 0.001).

HEMOGLOBIN LEVEL: The rise in the mean hemoglobin level at the end of 1 months of treatment was 10.19 ± 1.11 (7.6-12.5) compared to the pretreatment level of 9.08 ± 1.15 gm% (6.7-11.1 gm%). At 3 months of therapy, mean hemoglobin of the study group was 10.73 ± 1.04 gm% (8.6-12.9 gm%). The rise in hemoglobin rise at the end of 1 and 3 months of treatment was significant (p-value \leq 0.001).

ENDOMETRIAL THICKNESS: The mean endometrial thickness in the pre-treatment group was 8.55 ± 2.42 mm (3.49-14.93 mm). There was decrease in mean ET at 1 months 7.57 ± 2.76 (2.2-14.42 mm), 3 months 5.91 ± 1.65 (2.46-10.18) and 6 months 5.41 ± 1.78 (2.29-8.68) of treatment. The decrease in ET was found to be statistically significant (p-value \leq 0.001).

Complications	No.	%
Amenorrhea	13	28.26
Cervical Erosion & Discharge	1	2.17
Hypomenorrhea	4	8.70
Spotting	2	4.35
Ovarian cyst	2	4.35

Table 6: Complications (N=46)

COMPLICATION: Adverse effects included amenorrhea (28.36), cervical erosion & discharge (2.17%) and hypomenorrhea (8.70%). spotting (4.35%), ovarian cyst (4,35%) One of these 2 patients had the cyst at the beginning of treatment that persisted at the end also. In the during the course of treatment. The cysts had disappeared by the end of treatment in one patient and persisted in one Patient. One patient eventually underwent hysterectomy and histopathological examination found the cysts to be simple serous cyst.

Out of 54 patients, 46 womens with menorrhagia were recruited in study. Three (6.52%) patients had no response, four (8.7%) patients were lost to follow-up. During the one year study period, 1 (2.17%) of the patients underwent hysterectomy.

DISCUSSION: Medical management has always been the first therapeutic option to be tried and if it fails to show results, one can resort to surgical interventions. Hysterectomy should be the last resort in the management of DUB. The RCOG recommends beginning with medical management before resorting to surgical interventions. While hysterectomy offers an effective cure, it is suitable only for those, who have no further wish to conceive. The procedure involves major surgery with significant postoperative morbidity.^{11,12} Endometrial ablation techniques offer an alternative surgical treatment option with significantly reduced postoperative morbidity.¹³ They may be unsuitable for women

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wishing to retain their menstrual or reproductive function and require technical expertise not routinely available.

Medical treatment of menorrhagia should aim to relieve symptoms, improve quality of life and avoid the risk of surgery. The options available include NSAIDs, antifibrinolytics, daily hormonal pills, levonorgestrel intrauterine system (LNG-IUS) and selective estrogen receptor modulators (SERMS). Despite a decrease in MBL by 50%, many women remain menorrhagic when treated with tranexamic acid, mefenemic acid, flurbiprofen, norethisterone or ethamsylate and many are noncompliant due to daily dosing. The role of levonorgestrel intrauterine system in menorrhagia is well established and 80% reduction in MBL is seen, but its cost limits its widespread use, especially in developing countries, such as India.¹⁴

The present study was conducted to evaluate the efficacy and safety of ormeloxifene in the management of DUB. The study showed that. Decrease in no. of bleeding days was 76% in this study (Figure 2, Figure 3) as compared to 67.9% in study of Laxmi¹⁵ et al. All the patients in this study reported disappearance of clots in menstrual flow with the drug while the same was reported by 67.8% and 85.7% in Laxmi¹⁵ et al and Biswas¹⁶ et al study respectively. Improvement in dysmenorrhoea was observed in 73.91% patients in this study as against 81.8% and 78.3% in Laxmi¹⁵ et al and Biswas¹⁶ et al study respectively.

In this study (Table -5) shows there was a significant reduction in menstrual blood loss with ormeloxifene, as assessed by fall in PBAC score. The mean pretreatment 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). Kriplani et al¹⁷ conducted a pilot study in which the median PBAC score was significantly reduced from 338 to 80 at 2 months and to 5 at 4 months with a 99.7% reduction in mean blood loss. Dadich et al¹⁸ also found a significant reduction in median PBAC score (379 to 15), number of days of menstruation and number of sanitary napkins used after 6 months ormeloxifene therapy.

The results of our study (Table-5) suggests that The rise in the mean hemoglobin level at the end of 1 months of treatment was 10.19 ± 1.11 (7.6-12.5) compared to the pretreatment level of 9.08 ± 1.15 gm% (6.7-11.1 gm%). At 3 months of therapy, mean hemoglobin of the study group was 10.73 ± 1.04 gm% (8.6-12.9 gm%). The rise in hemoglobin rise at the end of 1 and 3 months of treatment was significant (p -value ≤ 0.001). The mean endometrial thickness in the pre-treatment group was 8.55 ± 2.42 mm (3.49-14.93 mm). There was decrease in mean ET at 1 months 7.57 ± 2.76 (2.2 \pm 14.42 mm), 3 months 5.91 ± 1.65 (2.46-10.18) and 6 months 5.41 ± 1.78 (.29-8.68) of treatment. The decrease in ET was found to be statistically significant (p -value ≤ 0.001).

Dhananjay et al¹⁹ studied 35 patients with DUB and found a statistically significant increase in hemoglobin concentration (8.26 to 10.59g/dl, $P < 0.001$) and a statistically significant decrease in endometrial thickness (9.83 to 4.89; $P < 0.001$) after 3 months of treatment with ormeloxifene of. Biswas et al¹⁶ studied 85 patient and found that the difference between pre-treatment and post-treatment median PBAC score of 97.2 and the rise in mean haemoglobin concentration of 1.3g/dl was statistically significant ($P < 0.001$)

Bhattacharyya et al²⁰ studied 180 cases of DUB, who had completed child bearing and were above 35 years. They were randomly assigned to ormeloxifene, progesterone and iron groups. Ormeloxifene group received ormeloxifene for 12 weeks. Norethisterone group received

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norethisterone for 12 days in every cycle for six cycles. Iron group was given as 60 mg of elemental iron daily. The subjects receiving ormeloxifene experienced a marked improvement (81.7%) in PBAC scores, reduction of blood clots and rise in hemoglobin levels.

Ormeloxifene was very well tolerated and practically there was no undesirable side effects. Amenorrhoea was the most common side effect seen in 13 patients (28.26%). Amenorrhoea was a common symptoms seen in different studie with a wide range of 8% to 42.9%.^{1,4,6}

The incidence of ovarian cyst with the use of ormeloxifene was 4.35% in this study (Table-6) as compared to 26.3% reported by Rajan et al.²¹ Rajan, 1996 reported that none of the patients with cysts complained of pain in abdomen or pelvic tenderness and all the cysts regressed spontaneously. The study was done to evaluate the contraceptive and non-contraceptive benefits of ormeloxifene (ormeloxifene). In our study, cysts were all painless, they regressed spontaneously in one patient and persisted in one patient. One was serous cysts as confirmed histopathologically after hysterectomy.

CONCLUSION: Ormeloxifene is very effective in improving all the parameters of blood loss in DUB including the no. of days of bleeding, no. of pads soiled and the passage of clots. Along with being effective, the drug has a good patient acceptability and compliance due to its minimal side effects, low cost (Compared to all alternative medical and surgical treatments) and simple dosage schedule.


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PBAC Scoring System

Pads		
1 point	For each lightly stained pad	
5 points	For each moderately stained pad	
20 points	For each completely saturated pad	
Tampons		
1 point	For each lightly stained tampon	
5 points	For each moderately stained tampon	
10 points	For each completely saturated tampon	
Clots/Flooding		
1 point	For each small clot (Australian 5 cent coin)	
5 points	For each large clot (Australian 50 cent coin)	
5 points	For each episode of flooding	

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Date of Submission: 11/12/2014.
Date of Peer Review: 12/12/2014.
Date of Acceptance: 02/01/2015.
Date of Publishing: 09/01/2015.