

## ABSTRACT

# **TO STUDY THE EFFICACY OF ORMELOXIFENE IN THE MEDICAL MANAGEMENT OF ABNORMAL UTERINE BLEEDING (AUB).**

### **OBJECTIVES:**

- 1) To evaluate the efficacy of ormeloxifene for abnormal uterine bleeding.
- 2) To study the acceptability of ormeloxifene.
- 3) To study the adverse effects of ormeloxifene used for abnormal uterine bleeding.
- 4) To study the recurrence of heavy menstrual bleeding in patients treated with ormeloxifene.

### **METHODS:**

About 100 patients attending the gynaec opd at Institute of obstetrics and gynaecology Kasturba Gandhi Hospital and Institute of Obstetrics and Gynaecology with complaints of heavy menstrual bleeding were included. Basic haemoglobin levels and platelet count was performed. Endometrial thickness by transvaginal ultrasonography and pictorial blood loss assessment chart scoring were studied.

### **INCLUSION CRITERIA :**

Patients presenting with abnormal uterine bleeding were recruited for study after detailed gynecological examinations and investigations to rule out any uterine pathology , congenital malformation and other organic causes for AUB.

### **EXCLUSION CRITERIA :**

1. Leiomyoma
2. Endometriosis
3. Malignancies of genital tract
4. Liver dysfunction
5. Heart disease
6. Coagulopathies

7. Renal disease
8. Pregnancy
9. IUCD /oral pill users
10. Lactating women in the first 6 months of postnatal period
11. Thyroid disorder
12. History of abortion within last 3 months
13. Hypersensitivity to drug

Patients meeting the inclusion criteria were given a trial ormeloxifene 60mg twice a week for 12 weeks and the above parameters were reviewed after a period of 3 months. Ormeloxifene 60mg once a week for 12 weeks and the same parameters were assessed. The repeated measures anova statistical tool was used to find the difference in three period. SPSS 20 version was used.

## **RESULTS:**

In this study about 100 patients were recruited after meeting the inclusion and exclusion criteria. The mean PBAC score, significantly reduced from 206.8788 to 94.4545 at the end of 3 months and further reduced to 77.9596 at the end of 6 months.(  $p < 0.0001$  significant ). On treatment with ormiloxifene , Hb increased by 1.38gm% ( mean Hb of 8.5470 gm% to 9.3800 gm% ) at the end of 3 months and further improved by 0.547gm % ( 9.300 gm% to 9.927gm% ) at the end of 6 months.

The mean endometrial thickness reduced from 11.0670 mm to 10.1034 mm at the end of 3 months and further reduced to 8.9560 mm at the end of 6 months( $p < 0 .05$ ) . So there was significant reduction in endometrial thickness, PBAC score in patients treated with ormiloxifene along with considerable improvement in Hb level thereby improving the quality of life of patients with AUB.

Out of these women about 4 % of women turned up to gynaecology op with recurrent heavy menstrual bleeding , who opted for trial with LNG-IUD . So ormiloxifene is cost effective drug in the medical management of AUB with few side effects like hypomenorrhoea , amenorrhoea , headache , nausea and with low recurrence rates . In developing country like India medical management with ormiloxifene can be a safer option

thereby reducing the financial burden by limiting the number of hysterectomies and the morbidities associated with surgery.

**KEYWORDS :** Abnormal Uterine Bleeding , Ormifloxifene , Selective Estrogen Receptor Modulator , Pictorial Blood Loss Assessment , Heavy Menstrual Bleeding.