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ORMELOXIFENE: UNRAVELING DURATION OF USE AND CONTINUATION TRENDS IN CONTRACEPTIVE SEEKERS

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ABSTRACT

Background: India's population growth demands effective contraception methods to reduce maternal and neonatal mortality. Limited access to contraceptives underscores the need for practical solutions. Ormeloxifene, a non-steroidal contraceptive, offers a unique approach without hormonal disruption. This study evaluates Ormeloxifene's use, focusing on continuation rates and reasons for discontinuation in diverse demographic groups. **Methods:** The study included 177 women aged 18-35, divided into postpartum, postabortal, and interval contraception groups. Ormeloxifene initiation details and follow-up visits were documented. Demographic, menstrual, obstetric, and medical data were collected, ensuring confidentiality. Participants were evaluated for menstrual complaints, side effects, and willingness to continue. **Results:** Ormeloxifene demonstrated a high continuation rate (98.8% at 3 months and 94.4% at 6 months). Menstrual complaints, primarily delayed menses, were common side effects. Religion and socioeconomic status influenced contraceptive practices. Ormeloxifene's safety and acceptability were comparable across different initiation periods. **Conclusion:** Ormeloxifene proved to be an acceptable and safe contraceptive option for women in postpartum, postabortal, and interval periods. Despite minor menstrual complaints, it had a high continuation rate, indicating its potential as an effective contraceptive method in diverse populations. Adequate counseling and information dissemination are crucial for managing expected side effects and ensuring user satisfaction.

KEYWORDS : Ormeloxifene, Continuation rate, Contraception

INTRODUCTION

India's urgent need for effective contraception is evident due to its rapid population growth. Despite the desire to control family size, numerous women lack access to contraceptives, leading to increased maternal and neonatal mortality rates. Government initiatives are vital in ensuring widespread access and diverse contraceptive choices. Indian scientists have made noteworthy contributions in enhancing contraceptive methods.[1] Oral contraception was introduced in 1960 with combined oral contraceptive pills. In 1967, a novel non-steroidal once-a-week pill called Ormeloxifene (Centchroman) was developed by the Central Drug Research Institute (CDRI), Lucknow. It was launched as 'Saheli' in 1995 under the National Family Planning Program and reintroduced as 'Chhaya' in 2016 as part of the National Family Planning Programme.[2]

Ormeloxifene prevents implantation by creating asynchrony between blastocyst movement and endometrial receptivity. Unlike other methods, it does not suppress ovulation or disrupt hormonal balance. Its convenient dosing and rapid return to fertility upon discontinuation make it highly effective and user-friendly.[3] Unlike prior research on pharmacokinetics, this study offers comprehensive insights into practical contraceptive use. The demographic profile of Ormeloxifene users, duration of use, continuation rates and reasons for discontinuation were studied.

MATERIAL AND METHODS

This prospective observational study was conducted for 12 months, from January 2021 to December 2021 in the Department of Obstetrics and Gynecology, Kasturba Hospital, Delhi, India. Women of the age group 18-35 years attending the Family Planning Clinic were selected. A total of 177 women aged 18-35 years were enrolled in the study during initial 3 months and were initiated on Ormeloxifene, who were then followed for a period of 6 months. Exclusion criteria were women with Polycystic Ovarian Syndrome, undiagnosed vaginal bleeding, chronic renal/liver disease or retained products of conception. The study was approved by the Institutional Ethical Committee. Participants provided voluntary and informed written consent with the option to withdraw anytime. Detailed histories (demographics, menstrual, obstetric, contraceptive, medical, personal) and baseline tests (blood counts, liver/renal function, blood sugar) were conducted for all cases, ensuring confidentiality.

Study Procedure

Women attending family planning clinic seeking contraception were provided counselling on various methods using informative materials and models. The study enrolled 177 women who initiated Ormeloxifene and agreed to participate, after giving written consent. Participants were divided into three groups based on the time of initiation of Ormeloxifene:

- In the Interval Period group: On the 1st day of menstrual bleeding.
- In the Postpartum group: At 6 weeks irrespective of menstrual cycle.
- In the Postabortal group: On the day of abortion.

Ormeloxifene initiation was done with tablet 30mg twice a week for first three months and then continued once a week. Women were advised to come for regular follow up visits at 1 month, 3 months and 6 months. During each follow up visit, pregnancy was ruled out and women were asked questions on experience, satisfaction, side effects and their willingness to continue the pill. Reasons for recommendation to others as well as factors leading to discontinuation were noted. Outcome was noted in terms of the following parameters; continuation rate, side effects, change in the bleeding patterns and breast milk if lactating, duration of use and reasons for discontinuation. The collected data were analyzed and statistically evaluated. Quantitative data were expressed as mean and standard deviation while qualitative data were expressed in percentage and differences between the proportions were tested by chi square test or Fisher's exact test. 'P'value less than 0.05 was considered statistically significant.

RESULTS

Age of the women varied from 18-35 years with mean age being 25.25±3.59 years. Among 177 study subjects, 114 women belonged to the Muslim religion, 58 of them were

Hindu and 5 belonged to the Sikh religion. A significant portion of the women, comprising 59%, came from the lower middle class. Additionally, 23% belonged to the upper lower class, while 8% and 9% represented the upper middle class and lower class, respectively. Most of the women (173) were residents of urban areas, with only 4 women living in rural regions. The study group was categorized based on education status using the modified Kuppuswamy scale. 22 women were found to be illiterate, while 155 had attended school.

The majority of women were multiparous i.e., 61%, while 39% of them were primipara. 91% women had normal BMI, 9% were overweight, and none were obese or underweight. The mean BMI was 22.67±1.53 kg/m2. 172 women had no prior history of any medical conditions, 2 had previously been treated for pulmonary tuberculosis, 1 had migraine, 1 was having hyperthyroidism, and 1 was hypertensive. 68 women were initiated on Ormeloxifene in the postabortal period, 67 in postpartum period and 42 in the interval period. 110 of the 177 study participants were non-lactating, 38 were only partially breastfeeding, and 29 were fully breastfeeding. Ormeloxifene continuation rate varied among the participants: all women persisted for the initial one month, 175 continued for 3 months and 167 women for 6 months. 8 subjects discontinued after 3 months of use and 2 dropped out of study (loss to follow up). 107 women were willing to continue Ormeloxifene after the study period (figure 1).

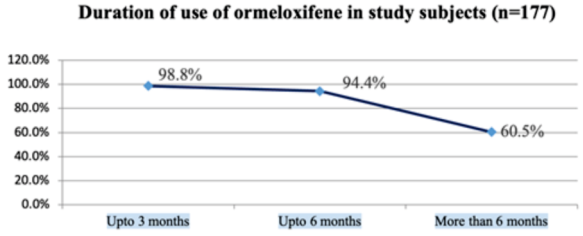

Figure 1: Duration Of Use Of Ormeloxifene In Months In 177 Subjects.

Most frequent side effect was menstrual complaints, with delayed menses being the most prevalent (19 women) followed by irregular menses in 16 women and amenorrhea in 3 women. Other side effects observed were nausea (2 women) , vomiting (1 woman) and headache (1 woman) which were observed only in small number of participants. At the beginning of the study, 170 women had regular menstrual periods and 7 had irregular cycles. 16 women experienced new onset irregular bleeding during the course of the study. The occurrences of irregular bleeding, breakthrough bleeding, and amenorrhea among the participants at different time points (1 month, 3 months, and 6 months) after starting Ormeloxifene is depicted in table 1.

Table 1: Menstrual Complaints With Use Of Ormeloxifene (n=177)

MENSTRUAL COMPAINTS	At 1 months (No.)%	At 3 months (No.)%	At 6 months (No.)%
Irregular bleeding	(3)1.7%	(8)4.5%	(5)3.0%
Breakthrough bleeding	(1)0.6%	(1)0.6%	0.0%
Amenorrhea	0.0%	(3)1.7%	(2)1.2%

After the study period, continuation patterns were analysed. Out of 177 women, 107 were willing to continue Ormeloxifene after study period and 68 women refused to continue due to side effects (the most frequent of which were menstrual complaints), desire of conception, psychosocial reasons or the lack of a continuing need for contraception. 2 participants could not be followed up. Table 2 summarizes the menstrual complaints and desire to continue Ormeloxifene during follow-up visits in all 3 groups.

Table 2: Menstrual Complaints And Willingness To Continue Ormiloxifene After The Study Period In All 3 Groups (n=175)

Menstrual complaints	Postpartum (n=66)	Postabortal (n=67)	Interval (n=42)
Irregular bleeding	7(10.6%)	5(7.5%)	4(9.5%)
Delayed menses	8(12.1%)	6(8.9%)	5(11.1%)
Willingness to continue Ormiloxifene	Postpartum (n=66)	Postabortal (n=67)	Interval (n=42)
Yes	44(66.7%)	34(50.7%)	29(69.1%)
No	22(33.3%)	33(49.3%)	13(30.9%)

DISCUSSION

Ormeloxifene is a highly effective oral contraceptive with very low failure rate. In our study, all women who received Ormeloxifene were divided into 3 groups post-abortal period, post-partum period and interval contraception. The 98.8 % of subjects continued Ormeloxifene for 3 months and 94.4% kept taking it for 6 months. However, the continuation rate dropped to 61.1% after 6thmonth. *Dewan et al* reported continuation rate to be 100% at 3 months and 98.3% at 6 months.[4] *Doke et al* reported continuation rate to be 100% at 3 months and 89% at 6 months.[5] The reason for discontinuation included side effects, desire of conception, psychosocial reasons. Most frequent side effect was menstrual complaints, with delayed menses being the most prevalent followed by irregular menses and amenorrhea. *Gupta M et al* also reported menstrual irregularities as frequent adverse effect, oligomenorrhoea being the commonest.[6] There existed no significant difference between the timing of initiation of Ormeloxifene i.e. postpartum, postabortal and interval period with the acceptability, safety profile and efficacy. Ormeloxifene had no deleterious effects on lactating mother with no effect on quantity of breast milk. Medical issues including hypertension, migraine without aura, thyroid disorders and women receiving anti-tubercular therapy were not adversely affected. Contraceptive failure was seen in one user (pregnancy was detected at 14-16 weeks) who had taken the pill in an interrupted manner. The pearl index calculated was to be 1.13. In a study by *Dewan R et al* there was one method failure and one user failure both at twelve months of the study in the Ormeloxifene group, with pearl index of 0.83.[4] The main drawback of study was its short duration (6 months), preventing a thorough evaluation of the return to regular menstruation and fertility among women using Ormeloxifene. A very small number of women with significant medical history were enrolled in our study; hence, the safety of Ormeloxifene in various medical conditions could not be strongly established.

CONCLUSION

Ormeloxifene is an acceptable contraceptive for majority of women in post-partum, post-abortal and interval periods, provided it is given with adequate pre-use counselling and patient information to alleviate the concern on expected side effects. The study also concludes that the most common side effect associated with Ormeloxifene use is menstrual changes, which mainly includes delayed menses and irregular bleeding, followed by amenorrhea. Religious practices and socioeconomic status played significant role in shaping contraceptive knowledge, attitudes, and practices. Ormeloxifene, being a non-hormonal and oral method is safe , well tolerated and has good acceptability due to lesser side effects.

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