

Research Correspondence

Real-world contraceptive performance of ormeloxifene among reproductive-age women

Sir,

India is currently the most populous country in the world with about 1.4 billion people, overtaking China in 2023¹. Despite India's expanding contraceptive options, unmet needs for spacing methods remain high among reproductive-age women². Hormonal contraceptives, while effective, often face compliance challenges due to side effects³. Ormeloxifene (Centchroman), a selective estrogen receptor modulator (SERM), offers a non-hormonal, reversible, and low-cost alternative^{4,5}. Although Ormeloxifene has been a part of India's National Family Welfare Programme, real-world data on its performance and user adherence remain limited⁶. This study aimed to assess the contraceptive efficacy, compliance, and tolerability of Ormeloxifene among reproductive-age women under tertiary-care settings.

This prospective observational study was conducted among 148 women aged 18–45 yr opting for Ormeloxifene for contraception. Participants were followed up for 12 months with monthly assessments of compliance, menstrual pattern, and adverse effects. Compliance was defined as adherence to the prescribed dosage schedule⁷. Pregnancy outcomes were recorded, and the Pearl Index was calculated. Self-reporting may have introduced recall bias. Data were analysed using descriptive statistics and chi-square tests to determine associations between demographic factors and conception rates. Approval was obtained from the Institutional Ethics Committee, and informed consent was obtained from all participants prior to the start of the study. The demographic characteristics, compliance patterns, menstrual changes, and conception outcomes are summarised in the table.

Among 148 women enrolled, compliance was recorded in 88.5 per cent. Three pregnancies occurred during the 12-month follow up period resulting in a Pearl Index of 2.1 per 100 woman-years. The most frequent side effects were menstrual irregularities (11.5%), headache (2%), vomiting (0.7%), and breast

Table. Demographic profile, compliance, menstrual pattern, side effects, and conception outcomes of participants (n=148)

Variable	Category	n (%)
Age group (yr)	19–23	73 (49.3)
	24–28	49 (33.1)
	29–33	21 (14.2)
	33–37	5 (3.4)
Occupation	Homemaker	143 (96.6)
	Others	5 (3.4)
Parity	Primipara	70 (47.3)
	Nullipara	42 (28.4)
	Multipara	36 (24.3)
Obstetric status	Interval	99 (66.9)
	Postabortal	45 (30.4)
	Postpartum	4 (2.7)
Compliance	Compliant	131 (88.5)
	Noncompliant (irregularity)	7 (4.7)
	Noncompliant (wanted conception)	2 (1.4)
	Noncompliant (lost to follow up)	5 (3.4)
	Stopped after conception	3 (2.0)
Menstrual pattern	Regular	109 (73.6)
	Delayed	28 (18.9)
	Amenorrhea	9 (6.1)
	Menorrhagia	2 (1.4)
Side effects	Headache	3 (2.0)
	Vomiting	1 (0.7)
	Breast complaints	1 (0.7)
Conception	Yes	3 (2.0)
	No	145 (98.0)

tenderness (0.7%). Discontinuation was mainly due to menstrual disturbances. No significant association was found between conception and age, parity, or obstetric status ($P > 0.05$).

The present study demonstrated that Ormeloxifene has satisfactory contraceptive efficacy and a favorable compliance profile in real-world use. The Pearl Index

(2.1) observed aligns with earlier Indian studies reporting rates between 1.6 and 2.5^{8,9}, confirming its reliability as a spacing method. Menstrual irregularities were the most common side effect, consistent with prior literature^{10,11}, but were generally mild and self-limiting. The non-hormonal mechanism, affordability, and easy reversibility make Ormeloxifene particularly suitable for women who cannot tolerate hormonal contraceptives¹². Despite its proven safety and inclusion in national programmes, postpartum and community-level uptake remains suboptimal^{13,14}, emphasising the need for counselling and awareness to enhance acceptance.

Overall, the findings of this study suggest that Ormeloxifene is a safe, effective, and reversible non-hormonal contraceptive with good compliance and minimal side effects. Integrating it into postpartum and community family planning initiatives may improve contraceptive choice and spacing outcomes in India^{15,16}. Future multicentric studies and digital health integration may strengthen implementation.

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