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Original Research Article

Exploring the efficacy of centchroman as a postpartum contraceptive: an observational study

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ABSTRACT

Background: Centchroman, a non-hormonal contraceptive, offers a safer alternative for postpartum women, particularly in India, where the responsibility of contraception largely falls on females. Despite its benefits, including minimal side effects and efficacy in pregnancy prevention, its adoption remains low. This study examines Centchroman's effectiveness as a postpartum contraceptive in eastern India
Methods: This prospective observational study (March 2017–February 2018) recruited postpartum women from SCB Medical College, Odisha, meeting inclusion criteria. Participants took Centchroman following a structured regimen, with follow-ups at 1, 3 and 6 months. The primary objective was to determine contraceptive efficacy. Secondary objectives were to assess compliance, satisfaction and adverse effects. Data were analysed using SPSS using Statistics (Version 23.0).
Results: During the study, 785 eligible participants were counselled and 247 consented to use Centchroman, resulting in an acceptance rate of 31.5%. Most were aged 25–29, Hindu (79.7%) and from rural areas (59.5%). Compliance was high, with 96.2% satisfaction by the third follow-up. Common adverse events included delayed periods and heavy bleeding, which decreased over time. Milk secretion reduction was minimal. The main reasons for discontinuation were living apart from their husband (4.8%) and fear of side effects (4.4%). Centchroman showed high adherence, safety and effectiveness as a postpartum contraceptive.
Conclusions: This study highlights Centchroman as a safe, effective, non-hormonal postpartum contraceptive with high acceptability. Minimal adverse effects make it suitable for lactating mothers.

Keywords: Centchroman, Family planning, Ormeloxifene, Postpartum contraceptive, Post-delivery contraception

INTRODUCTION

Fertility control plays a critical role in promoting the reproductive health of women from menarche to menopause. Sound knowledge of fertility control will help in reducing maternal mortality as well as reduce possible unsafe induced abortion practices.[1] The main aim of contraception is to promote reproductive health. It is estimated that in low and middle-income countries (LMICs) data of approximately 89,000 maternal deaths are associated with unintended pregnancy representing 30% of all maternal deaths in a year.[2] Hence Family planning is linked to a significant reduction in maternal mortality.

Population growth places significant pressure on the Earth's limited resources, further aggravating existing challenges. Thus the country's socio-economic development is also benefited when overpopulation is curbed.[3] In India, usually, the responsibility of

contraception is primarily on the female partner. India and its government have always been concerned about population growth and birth control. The proof is that India was the first nation in the world to launch constructive family planning programs in 1952.[4]

The postpartum period is a vulnerable period for the risk of unplanned pregnancy.[5] In the first postpartum year 65% of women have an unmet need for family planning. About 26% of women are using any method of contraception.[6,7] Lactational amenorrhoea in the postpartum period cannot be considered a safe alternative to any reliable contraceptive methods to prevent unwanted pregnancy. Around 10% of pregnancies occurred within 4 months of the postpartum period.[1]

Even though a basket full of choices for contraception is available, steroid Hormonal contraceptives are still considered a readily available and convenient temporary method of contraception preferred by many eligible couples in India. However, during the postpartum period combined oral contraceptive pills containing estrogen are not preferred because of its known effect on milk production and venous thromboembolism. Thus the need for a safer alternative for hormonal contraceptives has been felt.[8]

The first breakthrough in developing non-steroidal estrogen antagonists was led by Lener et al, in developing "MER-25", which antagonized the activity of both endogenous and exogenous estrogens. Based on this Central Drug Research Institute developed the first nonsteroidal compound Centchroman (Ormeloxifene) in 1967 which was launched for clinical use as an oral contraceptive.[9] It is a safe and reliable contraceptive agent ideally suited for spacing of birth in women who have no major medical contraindications. It is a second-generation selective Estrogen receptor modulator.

Weekly usage makes its use easy, feasible and hassle-free. It has the advantage of less frequent administration with a half-life of 168 hours as well as being quickly reversible. It prevents blastocyst implantation in the endometrium of the uterus and does not affect ovulation or the HPO axis. Centchroman has weak estrogenic action on bones but strong anti-estrogenic action on the uterus & breasts. Thus, besides its use as a contraceptive, it has also found use in breast cancer management. It is protective against Osteoporosis as well as cardiac ailments.[9,10]

It has been seen that the "Cafeteria approach" where health-care workers provide a variety of contraceptive choices for couples to choose from has a positive impact on their subsequent contraceptive usage.[11] Adding to the pre-existing basket of choices available, the Ministry of Health and Family Welfare introduced Centchroman as "Chhaya" in April 2016, which was distributed free of cost.[4,12] Its benefit is that it does not have the side effects that are displayed by steroidal contraceptives. It has an excellent therapeutic index and is quite efficacious in preventing pregnancy.[9,10] Centchroman (Chhaya) earlier marketed as "Saheli" has shown quite a low failure rate of only 1.63% (Pearl index: 1.83/HWY).[13] Despite this, Centchroman was underutilized.

In lactating women, it is excreted in milk in minimal quantities, which is considered unlikely to cause any hazardous effect in breastfeeding babies.[4] In multi-centric trials, it has shown no deleterious effect on the growth and development of babies. Hence, making it quite ideal for usage in the post-delivery period.[9,12] Despite being a non-hormonal and non-steroidal form of contraception, Centchroman has not gained popularity as a postpartum contraceptive.[14]

Limited data is available for Centchroman as a postpartum contraceptive. The present study was conducted to find the efficacy of Centchroman as a postpartum contraception in eastern India.

METHODS

Study type

This was a prospective observational study.

Study place

SCB Medical College, Odisha, India

Study duration

The study was carried out from March 2017 to February 2018.

All the eligible postpartum women who met the inclusion criteria and were willing to participate were recruited from the labour room and post-natal ward, Dept. of Obstetrics and Gynecology, SCB Medical College, Cuttack, Odisha.

Inclusion criteria

The inclusion criteria were women in 1st week of post-delivery, given consent for participation and follow-up.

Exclusion criteria

Participants who refused to participate or were not willing to use Centchroman, known cases of any chronic medical disorders, autoimmune diseases, immunocompromised patients, recent history of pregnancy-induced hypertension, jaundice, liver disease and intrauterine death were excluded from the study.

Participants were advised to take one pill of Centchroman (30 mg) twice a week for the first 3 months followed by one pill once weekly thereafter. The first pill was to be taken within 1 week of delivery of the baby. Follow-ups were scheduled at 1st month, 3rd month and 6th month post-delivery.

The primary objective of the study was to evaluate the efficacy of Ormeloxifene as a contraceptive in the postpartum period whereas the secondary objectives were to assess the degree of patient compliance, satisfaction and acceptability, maternal and neonatal adverse effects if any during the study period.

Breast milk adequacy was periodically assessed by assessment of the weight gain of the baby, number of wet and dry diaper changes in a day and subjective assessment of baby dehydration by the mother. The baby's milestones were assessed using the Milestone Moments checklist provided by the Centres for Disease Control and Prevention (CDC).[15]

During the study period, 785 eligible women were identified and 247 eligible women were given consent. Those 247 women were interviewed based on a pre-designed questionnaire.

The questionnaire elicited information regarding their age, educational status, religion, socioeconomic status as per modified Kuppuswamy classification (2007), obstetric status, menstrual history, past history as well as maternal and neonatal characteristics during the first and follow-up visits.

Statistical analysis

Data was collected in Microsoft Excel 2013 and analyzed using IBM SPSS Statistics (Version 23.0). Descriptive data were expressed in frequency and percentage.

RESULTS

In our study, we counselled 785 eligible participants during the study period but 247 participants were willing to use Centchroman and given consent to participate in the study. Hence the acceptance rate for the use of Centchroman in our study was 32% (Figure 1).

Table 1 shows, the majority of the participants were of the age group 25-29 years. Among the participants 79.75% were Hindu, 13.36% were Muslim and 6.88% belonged to other religions. Based on geographical area 59.51 % of females belong to rural whereas 40.48% were from urban areas. The majority of participants were from the lower middle class (42%) followed by the upper middle class (31%).

Most of the participants were primipara (67.1%) followed by parity two (25.9%). Twenty-seven participants had induced abortion in their reproductive life.

In the past, the majority of the participants (29.6%) utilized barrier methods as their primary contraceptive choice, followed closely by the use of oral contraceptive (OC) pills. Participants had a good knowledge (93.1%) of tubectomy and least (74.8%) of intrauterine contraceptive devices (IUCD).

Table 2 shows the compliance and complications during the follow-up period. On the first follow-up, it was observed that the adherence rate was 100%, none of them were pregnant and 10% of women developed complications including heavy bleeding, breast discomfort, vomiting and delayed period.

Reduced milk secretion was observed among 5.6% of participants and 95.6% of participants were satisfied with the use of Centchroman.

In their 2nd follow-up 221 participants continued to take Centchroman, 26 lost follow-up, one participant reported pregnancy, 16 (7.2%) developed some complications, milk secretion was reduced in 6 (2.7%), milestones of babies were normal in all participants and overall, 95.5% of participants were satisfied with the use of Centchroman.

On the 3rd follow-up, 213 participants were compliant to Centchroman intake, one patient reported pregnancy, 7 (2.8%) participants reported some complications, milk secretion was reduced in 5 (2%) of participants, babies of all the participants had a normal milestone and out of 213 participants 96.2 percent were satisfied with the use of Centchroman.

It was observed that the most common adverse event in first follow-ups is a delayed period (7.6 %), followed by heavy bleeding per vaginum (4%). Adverse events were more in 1st follow-up and subsequent reduction was observed in 2nd and 3rd follow-ups.

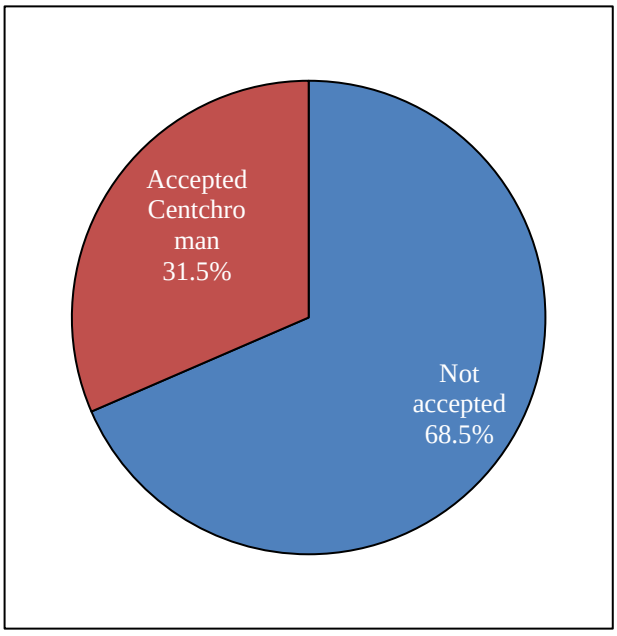

Figure 1: Acceptance of Centchroman.

Table 3 depicts the reasons for discontinuing Centchroman. The most common reason for stopping was living apart from their husband (4.8 %). The second most common reason was fear of side effects (4.4%). Other reasons given were wish to have more children (3.2%).

Table 1: Baseline socio-demographic parameter, contraceptive practices and knowledge of participants.

Variables	No of participants (n=247)	(%)
Age (in years)		
<20	9	3.7
20-24	87	35.2
25-29	107	43.3
30-34	30	12.1
>35	14	5.7
Religion		
Hindu	197	79.7
Muslim	33	13.4
Others	17	6.9
Residence		
Rural	147	59.5
Urban	100	44.5
Socio-economic class		
Upper	39	15.8
Upper-middle	77	31.1
Upper-lower	22	8.9
Lower middle	104	42.1
Lower	5	2.1
Parity		
1	166	67.1
2	64	25.9
3	17	7
Induced abortion		
0	220	89.1
1	20	8.1
2	5	2
3	2	0.8
Past contraceptive used		
Barrier method	73	29.6
IUCD	27	11
Natural method	55	22.2
Oral contraceptive pill	67	27.1
Not using any contraceptive	25	10.1
Knowledge of contraceptive		
Natural method	222	89.8
Barrier method	213	86.2
IUCD	185	74.8
O C Pill	217	87.8
Tubectomy	230	93.1
Vasectomy	205	82.9

Table 2: Compliance and complications during follow-up.

	1st follow-up (n=247)	2nd follow-up (n=221)	3rd follow-up (n=213)
Compliance	247 (100%)	221 (89.5%)	213 (86.2%)
Failure	0 (0%)	1 (0.41%)	1 (0.4%)
Adverse events	25 (10.1%)	16 (7.2%)	7 (2.8%)
Type of adverse event			
Heavy bleeding	6 (2.4%)	4 (1.8%)	2 (0.9%)
Scanty bleeding	1 (0.4%)	0 (0%)	1 (0.5%)
Delayed period	12 (4.9%)	6 (2.7%)	1 (0.5%)

Continued.

	1st follow-up (n=247)	2nd follow-up (n=221)	3rd follow-up (n=213)
Breast discomfort	2 (0.8%)	1 (0.5%)	1 (0.5%)
Vomiting	2 (0.8%)	2 (0.9%)	0 (0.5%)
Pain abdomen	1 (0.4%)	1 (0.5%)	1 (0.5%)
Head reeling	1 (0.4%)	2 (0.9%)	1 (0.5%)
Milk secretion			
Adequate	233 (94.3%)	215 (97.3%)	242 (98%)
Reduced	14 (5.7%)	6 (2.7%)	5 (2%)
Milestone of baby			
Normal	247 (100%)	221 (100%)	213 (100%)
Not appropriate for age	0 (0%)	0 (0%)	0 (0%)
Satisfaction overall			
Yes	236 (95.6%)	211 (95.5%)	205 (96.2%)
No	11 (4.4%)	10 (4.5%)	08 (3.8%)

Table 3: Reason for discontinuation.

Reason for discontinuation	Number (n=34)	%
Further childbearing	8	3.2
Fear of side effects	11	4.4
Not staying with husband	12	4.8
Reason not specified	2	0.8

DISCUSSION

The use of Centchroman as a postpartum contraceptive presents both opportunities and challenges. Its non-hormonal nature makes it a valuable alternative for the available contraceptive options, particularly for women who are concerned about the hormonal side effects of other oral contraceptives.

In our study, the acceptance rate of Centchroman as a postpartum contraceptive was 31.5%, while 69.5% of participants declined its use, citing various reasons such as its status as a new drug, lack of awareness about it and concerns about unknown side effects. The study regarding the acceptance rate of Centchroman is limited. In recent studies showing the acceptance rate has ranged from 2.9 to 77.5 percent.[14-17] The wide variation in acceptance rate could be due to different population characteristics of participants. Sarkar et al, in their study, reported an acceptance rate of 2.9% during enrolment, however, the acceptance improved to 81.7% after a three-phase quality improvement initiative with Plan-Do-Study-Act (PDSA) cycles.[17] This highlights the crucial role of healthcare professionals in providing thorough counselling to participants regarding postpartum contraception.

Most of the women participating in our study were aged 25-29 years which is comparable to studies conducted by Singh et al. and Nair et al, this could be due to early age of marriage and early childbearing in eastern India.[10,18] Majority of participants were Hindu, from rural areas and of lower middle class which was comparable to the study conducted by Mohapatra et al, in Eastern India.[19] We observed that the compliance rate for the Centchroman use was more than 86% and the failure rate was less than one percent during the entire period of follow-up, which could be due to proper counselling and weekly dosage pattern of Centchroman as compared to a daily dose of other contraceptive pills. Sarkar et al. in their study reported a similar compliance rate (78.6-97.6%).[17] In a scoping review, Kabra et al, reported effectiveness of 93% to 100% and a failure rate of 2.6% to 10.2% among users of centchroman.[12]

The adverse event rate observed in the present study was 10 %, 7.2% and 2.8% on its use in 1st, 3rd and 6th month respectively. The commonest adverse event observed was a delayed menstrual cycle during the first three months of use followed by heavy menstruation thereafter. Reduction of symptoms was noted with continuous use of Centchroman. A similar adverse event profile was observed by Kamboj et al, Singh et al and Kabra et al, in their study.[9,10,12]

Milk production decreased in 2% to 5.7% of women, but all babies reached their developmental milestones as expected. Over 95% of users were satisfied with Centchroman and these findings align with existing research.[9,10] The major cause of discontinuation was non-cohabitation with the husband.

A key strength of this study is the diverse participant population, with a significant representation from rural areas. Given that the unmet need for contraception is

higher in rural communities, the findings provide valuable insights into contraceptive preferences among women in these settings.

This study has some limitations that should be acknowledged. Firstly, as an observational study without a comparator group, the findings may be subject to potential biases and lack direct comparative analysis. Additionally, the small sample size may limit the generalizability of the results. The study was conducted in a single-centre setting in Eastern India, which may restrict the applicability of findings to broader populations. Lastly, the relatively short duration of the study may have constrained the ability to assess long-term outcomes and contraceptive continuation rates.

Future research with larger, multi-centre studies and longer follow-up periods would be beneficial in addressing these limitations and strengthening the evidence for Centchroman as a postpartum contraceptive option.

CONCLUSION

This observational study evaluated the efficacy, safety and acceptability of Centchroman as a postpartum contraceptive. The findings suggest that Centchroman is a viable option for postpartum contraception, offering non-hormonal benefits and ease of use. The study observed a favorable safety profile with minimal adverse effects, making it a suitable choice for postpartum and lactating mothers. Furthermore, the acceptability and continuation rates indicate that Centchroman can be an effective addition to postpartum family planning options.

However, given the limitations of observational studies, further randomized controlled trials are recommended to validate these findings and assess long-term impact. Comprehensive awareness campaigns and educational initiatives may also enhance acceptance and adherence among postpartum women.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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