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Original Research Article

A study of Centchroman users with special reference to its contraceptive benefit

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ABSTRACT

Background: Centchroman (INN: Ormeloxifene), was developed at CDRI, Lucknow in 1967. This drug was finally approved and licensed in 1991 and launched as Saheli and Choice-7 for marketing in 1992. The Ministry of Health and Family Welfare, India has now introduced centchroman in national family planning programme under the trade name "Chhaya" from April 2016. Centchroman is a novel nonsteroidal contraceptive that inhibits the fertilised ovum from implantation and thus prevents pregnancy. The aim of this study was to assess the effectiveness, side effects, discontinuation rates and failure rate among the users of Centchroman (Chhaya).
Methods: The retrospective study was conducted by reviewing the records of Centchroman (Chhaya) contraceptives acceptor over the period of one year from September 2017 to August 2018 in family welfare clinic of Department of Obstetrics and Gynecology at Tomo Riba Institute of Health and Medical Science, a tertiary level center in Naharlagun, Arunachal Pradesh, India.
Results: A total of 146 women were evaluated for the study. Majority of the women were in the age group of 20-30 years (76.02%) with mean age of 26 years. Most of the centchroman acceptors were multipara (74.65%) and women in post-abortion (38.35%) and postpartum group (36.3%). Duration of use ranged from 3 months in 146 women to 12 months in 98 women. The discontinuation rate was 31.5%. The major menstrual complaint was delayed menstrual cycle in 15.06% women and irregular cycle in 10.95%. Of the 146 women in the study group, pregnancy occurred in 3 women. Pearl index calculated for centchroman was 2.05/HWY.
Conclusions: Centchroman is a non-steroidal, non-hormonal oral contraceptive drug with good therapeutic efficacy and a favourable side effect profile. Centchroman has an important place in postpartum contraception due to its safety profile in breastfeeding women.

Keywords: Centchroman, Chhaya, Contraceptive, Failure rate, Ormeloxifene

INTRODUCTION

Family Planning has been of deep interest to the Government of India almost since independence in 1947. The first structured family planning programme was launched by the Ministry of Health in 1952. The ministry in its strategy and plan for family planning called upon Central Drug Research Institute, Lucknow (CDRI) in 1960 to develop suitable contraceptives for family planning. CDRI therefore decided to focus its emphasis on exploring non-steroidal antiestrogens as contraceptives. During this period the classical paper of Lerner et al, was published describing the first non-steroidal estrogen antagonist, MER-25, which antagonized the activity of both endogenous and exogenous estrogens (both steroidal and non-steroidal) but were not anti-ovulatory and prevented pregnancy in rats when given post-coitally.[1] The lead provided by

MER-25 seemed to meet these requirements, and the Institute chose to design and develop non-steroidal post-coital contraceptives based on the MER-25 lead.[2]

Centchroman (INN: Ormeloxifene), a reversible post-coital/weekly oral contraceptive (half-life of about 168 hours), was finally designed and developed at CDRI, Lucknow. It was synthesized in 1967 and completed pre-clinical in 1978 and clinical studies in 1989. This drug was finally approved and licensed in 1991 to Hindustan Latex and Life Care Ltd, Thiruvananthapuram and launched as Saheli and Choice-7 for marketing in 1992. The Ministry of Health and Family Welfare, India has now already introduced Centchroman in National Family Planning Programme under the trade name "Chhaya" for free distribution from April 2016. It is the first contraceptive used in the National Family Welfare Programme discovered and developed in India, and perhaps the first non-steroidal contraceptive in use in the world.[3,4]

The main effect of Centchroman appears to be on endometrial receptivity. Centchroman appears to exert its contraceptive action by producing asynchrony between blastocyst movement and endometrial receptivity to blastocyst resulting in inhibition of implantation in the uterus. It is the only contraceptive which neither suppresses ovulation nor interferes with the hypothalamic-pituitary-ovarian axis. It has high level of safety and is virtually free from side effects except for a delay in about 8% menstrual cycles which is not confined to any women/cycle.[5-8] The published data with Centchroman at the 30 mg biweekly cum weekly dose schedule has reported an acceptable pregnancy protection (Pearl index : 1.83) and cumulative pregnancy protection by life table analysis at 12 months of 1.63±0.74.[8-10]

The aim of this study was to assess the effectiveness, side effects, discontinuation rates and failure rate among the users of Centchroman (Chhaya) in our tertiary center after its introduction in 2016 under National Family Planning Programme. Moreover, there are very few studies and literature available on efficacy of Centchroman as contraceptives other than published report from Central Drug Research Institute, Lucknow (CDRI).

METHODS

The retrospective study was conducted by reviewing the records of Centchroman (Chhaya) contraceptives acceptor and users in family welfare clinics over the period of one year from September 2017 to August 2018 in the Department of Obstetrics and Gynecology at Tomo Riba Institute of Health and Medical Science, Naharlagun, Arunachal Pradesh, India.

Centchroman is available as colourless, odourless tablets of 8 in a pack. It is supplied by Hindustan Latex. All eligible women (18 to 40 years) coming to family welfare clinic and choosing the Centchroman (Chhaya) are given one pill (30 mg) twice a week for first three months, followed by once a week thereafter. Starting from fourth month, the pill was to be taken once a week on the first pill day and should be continued on the weekly schedule regardless of her menstrual cycle. Centchroman first pill was started on 1st day of menstrual bleeding and the second pill 3 days later in interval cases. If the first tablet is taken on a Sunday, the second tablet should be taken on a Wednesday. Following abortion, the patient was instructed to take the tablet on the day of abortion. Postpartum patients are instructed to take the tablet on the day of the postnatal visit, i.e. at 6 weeks irrespective of whether cycles are resumed or not. As per family welfare programme protocol, Centchroman pills are given for only 3 months course in every visit to get feedback of follow up, discontinuation rate, any side effects and failure on follow up visit. Women with polycystic ovarian disease, cervical hyperplasia, severe allergic state, recent jaundice history or liver disease, tuberculosis and renal disease were excluded and not given Centchroman.

Statistical analysis

All data was collected on a proforma and entered into computer using SPSS version 10 for analysis. Data from the study was analyzed in relation to the age at acceptance, parity, obstetric status at acceptance, failure rate, discontinuation rate and any adverse effects.

RESULTS

During the study period of 1 year from September 2017 to August 2018, 146 women who received Centchroman (Chhaya) were evaluated for the study for its contraceptive efficacy. The demography of women in the study group are shown in Table 1. The mean age of women was found to be 26 years. Majority of the women in study were multipara (74.65%) and primipara were 25.34%. Most of the women were from urban area (56.84%).

Table 1: Demography of study group.

Sr. no.	Parameter	Frequency
1	Mean age (years)	26 years
Parity		
2	Multipara	109 (74.65%)
	Primipara	37 (25.34%)
3	Rural	63 (43.15%)
	Urban	83 (56.84%)

As shown in Table 2, the age pattern ranged from 18 to 40 years with maximum number in the age group of 20-30 years, i.e.111 (76.02%).

The obstetrics status at the time of acceptance are shown in Table 3. The maximum number of acceptors were

women in post abortion group of 38.35%. Postpartum groups were 36.3% and interval were 25.34%.

Table 2: Age distribution.

Sr. no.	Age	N (%)
1	18-20 years	15 (10.27%)
2	20-30 years	111 (76.02%)
3	30-40 years	20 (13.69%)

Table 3: Obstetrics status at acceptance.

Obstetric status	Number	Percentage
Postpartum	53	36.3
Interval	37	25.34
Post-abortion	56	38.35

Table 4: Duration of Centchroman use in study group.

Duration (Months)	Number	Percentage
3	146	100
6	130	89.04
9	118	80.82
12	98	67.12

Table 4 shows the duration of use by number of women in one year. All 146 women in the study group used Centchroman for the first 3 months. Out of total 146 women, 98 continued and used Centchroman till the end of one year. Three women got pregnant and remaining 45 dropped out and discontinued. The discontinuation rate was 31.5%. The major cause for discontinuation of Centchroman was menstrual irregularity mainly delayed cycles. Other causes included inability to come for follow up from rural area, desire to conceive or adoption of an alternate method.

Table 5: Failure rate.

Particulars	N (%)	Pearl index
Pregnancy	3 (2.05%)	2.05

Table 5 shows the failure rate of Centchroman (Chhaya) in our study. Three women (1 in post abortion and 2 in interval user) in the study group became pregnant in the first 3 months. This was mainly user failure where the patient had either missed the tablet or has not used an additional protection for the first month. The Pearl Index calculated is 2.05.

Table 6: Menstrual changes in study group.

Sr. no.	Parameter	N (%)
1	Delayed menstrual cycle	22 (15.06%)
2	Amenorrhea	6 (4.11%)
3	Irregular menstrual cycle	16 (10.95%)

The major menstrual complaint was delayed cycles seen in 15.06% of the acceptors as shown in Table 6. 10.95% of the acceptors experienced irregular cycles and 4.11% experienced amenorrhea. In case of delay in menstruation, a pregnancy test was done after 2 weeks of delay.

Systemic side effects were very few ranging from headache (2 cases) and vomiting (1 case) as shown in Table 7.

Table 7: Adverse effects in study group.

Sr. no.	Adverse effect	N (%)
1	Headache	2 (1.37%)
2	Vomiting	1 (0.06%)

DISCUSSION

In 1951, India was the world's first nation to launch the Family Planning Programme. Over the years India's Family Planning Programme has evolved with the shift in focus from merely population control to more critical issues of saving lives and improving the health of mothers and child. Cleland et al, in their study reported that Family Planning can avert the 30% of maternal deaths and 10% of childhood deaths.[11] Documented evidence shows that expansion and introduction of new methods in the existing basket of choices of contraceptive method in developing countries has a positive relationship with contraceptive use. Considering the expansion of basket of choice and resurgence of interest and experience in postpartum family planning the Ministry of Health and Family Welfare, India has now introduced Centchroman in National Family Planning Programme under the trade name "Chhaya" for free distribution from April 2016. It is devoid of gross pharmacological effects seen with steroidal oral contraceptives and has excellent therapeutic index and provides acceptable pregnancy protection in the postcoital and weekly schedule in women.[7-10]

Majority of the women (76.02%) were in the age group of 20-30 years and were comparable with reports of Singh et al, and Nair et al.[9,12] Women above 40 years were excluded from the study. Multiparous women (74.65%) were more in our study which was in contrast to report by Nair et al, where 93% of the women were primipara.[12] The reason could be because of regional variation as people residing in hilly and Himalayan region prefers more children and larger family size.

Maximum numbers of acceptors were seen in women in post abortion group (38.35%) and postpartum (36.3%), which was comparable with other studies.[10,12] The women in postpartum and post-abortal group forms the best client for Centchroman contraceptives since it is non hormonal, requires less dosage interval and safe option for breastfeeding mother.

All 146 women in the study group used Centchroman for the first 3 months. Three women got pregnant and remaining 45 dropped out and discontinued. The discontinuation rate was 31.5% which was quite higher than other study of 15%.[12] Major reason for discontinuation of Centchroman was mainly because of delayed menstrual cycles. Other causes included inability to come for follow up from rural areas, desire to conceive or adoption of an alternate method.

Centchroman (Chhaya) marketed as Saheli has a failure rate of only 1.63% (Pearl index: 1.83/HWY).[8-10] Three cases of pregnancies were reported, 2 women in interval and 1 in post-abortion user. Failure was not found in postpartum group users. The Pearl Index of the present study was found to be 2.05/HWY which was slightly higher than the claims put forward by the literature and company.

The major menstrual complaint was delayed menstrual cycles seen in 15.06% of the acceptors and this was quite higher comparing the 8% of literature.[8,9] Amenorrhea was seen in only 6 (4.11%) women who were in postpartum group. Systemic side effects were very few ranging from headache (2 cases) and vomiting (1 case) which was comparable with the normal incidence of such happening in general population.

CONCLUSION

Centchroman is a non-steroidal, non-hormonal oral contraceptive drug with good therapeutic efficacy and a favourable side effect profile. The compliance rates of therapy with this drug are also good due to convenient dosage schedule. Centchroman has an important place in postpartum contraception due to its safety profile in breastfeeding women. Proper strategies by making it easily accessible to women at various stages of reproductive cycle, giving counselling and follow up messages in complete and easily understandable language will improve the contraceptive pill user in India.

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REFERENCES

1. Kamboj VP, Ray S, Anand N. Centchroman: A safe reversible postcoital contraceptive with curative and prophylactic activity in many disorders. Front Biosci (Elite Ed). 2018;10:1-14.
2. Lerner LJ, Holthaus JF, Thompson CR. A nonsteroidal estrogen antagonist 1-(p-2-diethylaminiethexyphenyl)-2-phenyl methoxyphenylethanol. Endocrinol. 1958;63(3):295-318.
3. Kumar N, Pant G, Kulkarni SR. The journey of the world's first non-steroidal contraceptive from Academic venture to National family programme. Available at: www.currentscience.ac.in/Volumes/115/09/1638.pdf. Accessed on 15th September 2019.
4. Oral Contraceptive Pills - National Health Mission. Available at: https://nhm.gov.in/New_Updates_2018/NHM_Components/RMNCHA/Family_planning/Schemes_&_Guidelines/Oral_Contraceptive_Pills.pdf. Accessed om 15th September 2019.
5. Kamboj VP, Kar AB, Ray S, Grover PK, Anand N. Antifertility activity of 3,4-trans-2,2-dimethyl-3-phenyl-4-p(β-pyrolidinethoxy)-phenyl-7-methoxychroman. Indian J Exp Biol. 1971;9:103-4.
6. Kamboj VP, Setty BS, Chandra H, Roy SK, Kar AB. Biological profile of Centchroman: a new post- coital contraceptive. Indian J Exp Biol. 1977;15:1144-50.
7. Lal J, Asthana OP, Nityanand S, Gupta RC. Pharmacokinetics of centchroman in healthy female subjects after oral administration. Contracept. 1995;52(5):297-300.
8. Kamboj VP, Ray S, Dhawan BN. Centchroman. Drugs Today. 1992;28:227-32.
9. Singh MM. Centchroman, a selective estrogen receptor modulator, as a contraceptive and for the management of hormone-related clinical disorders. Med Res Rev. 2001;21(4):302-47.
10. Nityanand S, Kamboj VP, Chandrawati, Das K, Gupta K, Rohtagi P, et al. Contraceptive efficacy and safety of Centchroman with biweekly-cum-weekly schedule. In: Current concepts in fertility regulation and reproduction, Eds: CP Puri, PFA VanLook New Delhi, Wiley Eastern Ltd; 1994:61-68.
11. Cleland J, Bernstein S, Ezeh A, Faundes A, Glasier A, Innis J. Family planning: the unfinished agenda. Lancet. 2006;368(9549):1810-27.
12. Nair HS, Jayasimhan P. A prospective study of centchroman users with special reference to its contraceptive benefit. J. Evid Based Med Healthc. 2016;3(98):5374-80.

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