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Original Research Article

## QI initiative to improve utilization of centchroman: a non-steroidal contraceptive

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### ABSTRACT

**Background:** The nonsteroidal contraceptive centchroman is manufactured in India. It was included in family welfare programme in April 2016 by the Ministry of Health and Family Welfare, Government of India. However, national statistics indicated its low utilization at all levels of healthcare. Objective was to identify the reasons for underutilization of centchroman in the family planning clinic, and in the postpartum period, and to implement corrective measures to improve its utilization at a tertiary hospital.

**Methods:** The study was conducted in the department of obstetrics and gynecology at a tertiary care hospital from September 2019 to January 2022. A quality improvement action team was constituted to undertake root cause analysis. Important corrective factors were insufficient focused counselling for centchroman as contraceptive, insufficient sensitization of doctors and nurses, inconsistent supply of tablets, lack of clarity about side effects of centchroman among healthcare workers. Tablets were not readily available to postpartum women at home, which was also a contributing factor. There were the following changes implemented: sensitization of the healthcare workers, daily focused FP counselling of women in outpatient clinics and postnatal wards, and measures to ensure a continuous supply of tablets. At discharge, eligible postpartum women were given a three-month supply of tablets for ready access. ASHA (accredited social health activist) workers who are engaged in other governmental health initiatives were included in the loop to maintain contact and supply tablets to women initiated on centchroman.

**Results:** Contraceptive utilization increased from 0.5-0.7% at beginning of the study to 29% by incorporating the solutions. Failure of contraception occurred in one user. Pearl index for centchroman in our study was 0.22%.

**Conclusions:** Simple, practical solutions identified through quality improvement initiatives resulted in improved coverage and utilization of contraceptive. This study can be an important example for problem solving of challenges in low resource settings.

**Keywords:** Oral contraceptive, Ormeloxifene, Quality improvement

### INTRODUCTION

According to the recent National Family Health Survey (NFHS-5), the unmet need for family planning (FP) in India is estimated at 8.4% and spacing between two childbirths at 3.6% of births.<sup>1</sup> Immediate postpartum contraception ensures that the woman can start the method before her first ovulation. When contraception provision is delayed, women are less likely to access it with the

attendant risk of unplanned pregnancy and short inter-pregnancy intervals.<sup>2</sup> In a study on postpartum unintended pregnancies, it was found that 86% of these pregnancies were due to non-use of contraception and more than half ended in induced abortion.<sup>3</sup>

Centchroman (INN: ormeloxifene) is a reversible weekly non-steroidal oral contraceptive pill synthesized in 1967 by Central Drugs Research Institute (CDRI), Lucknow,

India. Following clinical trials, it was approved and licensed for use in 1991. The Ministry of Health and Family Welfare, India introduced centchroman in national family planning programme under the trade name “Chhaya” for free distribution in April 2016. It is prescribed at 30 mg biweekly for 3 months followed by once weekly dose. By producing asynchrony between blastocyst movement and alteration in endometrial receptivity, it inhibits implantation. It neither suppresses ovulation nor interferes with the hypothalamic-pituitary-ovarian axis. Delay in about 8% menstrual cycles has been reported with its use.<sup>4</sup> Studies reported that centchroman does not seem to inhibit ovulation although it may delay it; it exerts its contraceptive effect mainly due to its action on cervical mucus and endometrial affecting sperm transport and implantation<sup>5</sup>. The published data for centchroman have reported pearl index at 1.83-4.2/HWY.<sup>6,7</sup>

The University College of Medical Sciences and Guru Teg Bahadur Hospital is a busy tertiary facility located in East Delhi. An assessment of the baseline centchroman prescriptions was evaluated for year 2018-19 which revealed that the usage was only 0.5-0.7% of all contraceptives of which there were no prescriptions in postpartum period. Given the low utilization of a freely available non-steroidal contraceptive in the Government family welfare programme, the study was planned.

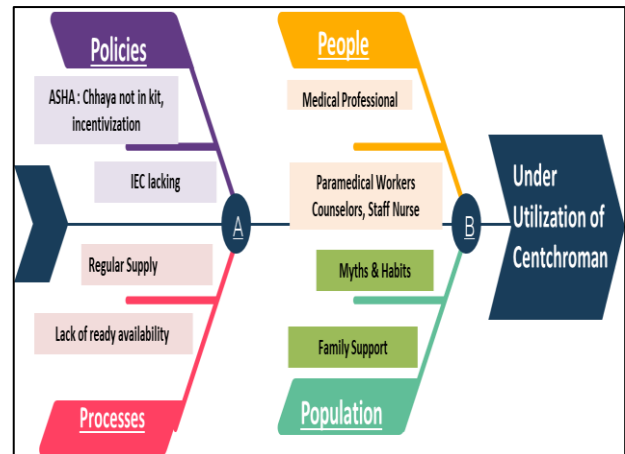
Objective of this study was to identify the reasons for underutilization of centchroman as a contraceptive in the family planning clinic, as well as in the postpartum period, and implement measures to improve its use.

## METHODS

The study was conducted in the department of obstetrics and gynecology at UCMS and GTB Hospital, Delhi from September 2019 to January 2022. A quality improvement action team was formed with representatives of faculty members, residents and nursing officers posted in family planning to address the problem of low centchroman prescriptions in the outpatient clinic as well as in postnatal wards. Fishbone analysis (Figure 1) was undertaken. By analysing root causes, solutions were identified (Figure 1). Incorporating these led to an increase in prescriptions to 29%. A medical social worker posted for an ongoing contraceptives project was assigned the task of counselling of postpartum women.

Main reasons for low prescriptions are grouped under 1) people medical (doctors) and paramedical workers including staff nurses, 2) population, 3) processes, 4) policies.

PDSA (plan-do-study-act) cycles were used to conduct and analyse the various change ideas. The team members met at regular intervals (weekly) to investigate the progress made and identify the issues that needed to be addressed. Data were tabulated according to the standards for quality improvement reporting excellence.



**Figure 1: Fish bone analysis and remedial measures.**

### Eligibility

Outpatient and postpartum women who elected to use centchroman and consented for follow up for at least 12 months (either hospital visit or telephonic) were considered eligible for the contraceptive.

### Contraindications

Severe allergic states and women with recent history of jaundice or liver disease, tuberculosis and renal disease, were excluded.

### Measurements

Percentage of all deliveries (vaginal and caesarean) and percent of all women seeking contraception in family planning clinics receiving centchroman were used as process indicators. The data collection was done by the ICMR project staff. The frequency of data collection was kept to daily.

### Analysis

Data was collected on a proforma and analysed using STATA version 12 for analysis.<sup>8</sup>

### Corrective measures undertaken

Informal training of healthcare workers including doctors was instituted.

Patients and their relatives were counselled regarding the availability of centchroman and its advantages. This could be done better in the postpartum wards.

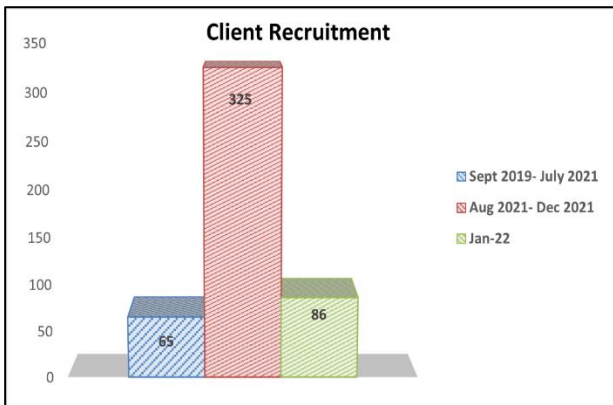
Centchroman pills for a period of 3 months was handed over to the parturient women upon discharge from the hospital with the instruction to start the pill upon receiving a phone call from the healthcare worker to confirm that there are no attendant complications of delivery. The pills were started at 2 weeks postpartum.

ASHA (accredited social health activist) worker associated with the patient was contacted and included in the loop to maintain contact and supply of pill.

The supply chain was closely monitored to maintain a buffer stock.

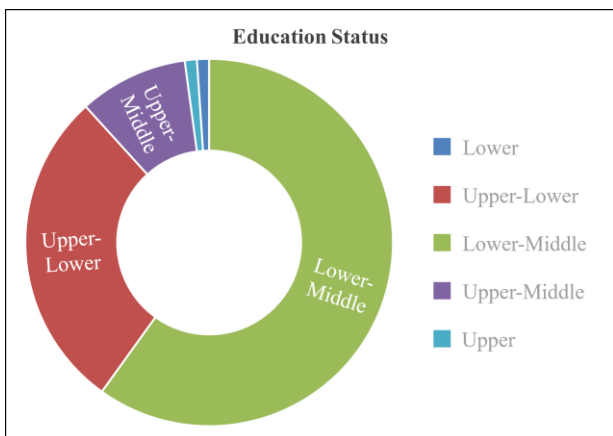
**RESULTS**

Important reasons included inadequate sensitization and training of doctors and nurses on centchroman, postpartum women lacked ready access to centchroman pills at home, dependence of the parturient on her husband and family members on the decision to initiate contraception, and inconsistent supply of centchroman at the hospital.



**Figure 2: Recruitment of clients for centchroman.**

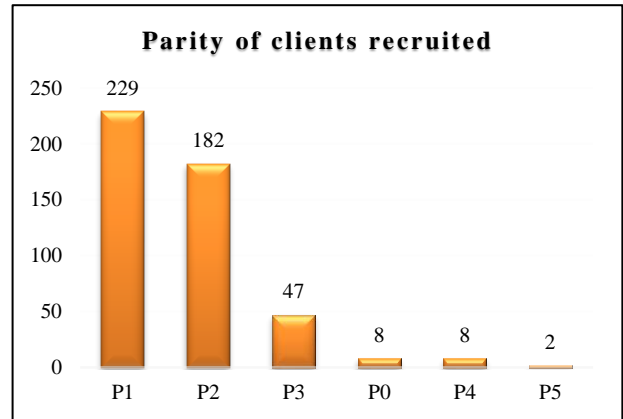
The initial utilization (2018-19) was 0.5-0.7 %. Following a root cause analysis, the bottlenecks were addressed, and the utilization increased to 29% (Figure 1 and 2) at 3 months and 30-35% at 1.5 years. The study enrolled 476 women. The mean age of recruitment was 26±5 years. The client characteristics are illustrated in Figures 3-6.



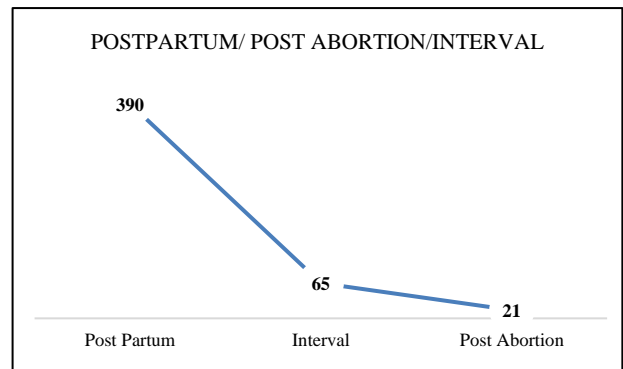
**Figure 3: Education status of clients on centchroman.**

Covid pandemic and other reasons limited the number of women who could be followed up to 237 (Figure 7). The discontinuation rate was 4.87% (n=19). Most

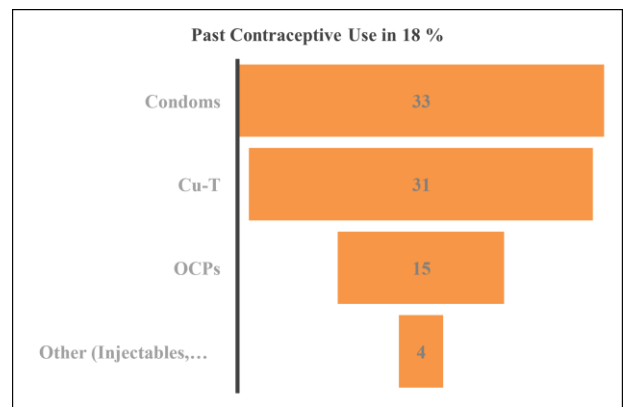
discontinuations occurred after 3 months of use. Menstrual cycle alteration [delayed (11.6%) and irregular cycle (6.5%)] were the primary reasons for discontinuation, as were abdominal pain, weight gain, gastritis, body ache, backache, and vaginal discharge (Figure 8). Seventy-six women did not start the pills at home. The reasons included disapproval from her husband and other family members, particularly her mother-in-law, forgetfulness, and lack of motivation. At the end of the first year, 97 women were on centchroman, and three women continued for two years. Pregnancy occurred in 1 woman after 2 months of use. Pearl index calculated for centchroman was 0.43%.



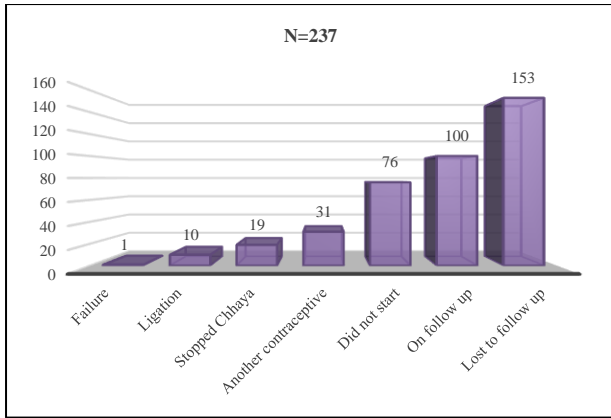
**Figure 4: Parity of clients who accepted centchroman.**



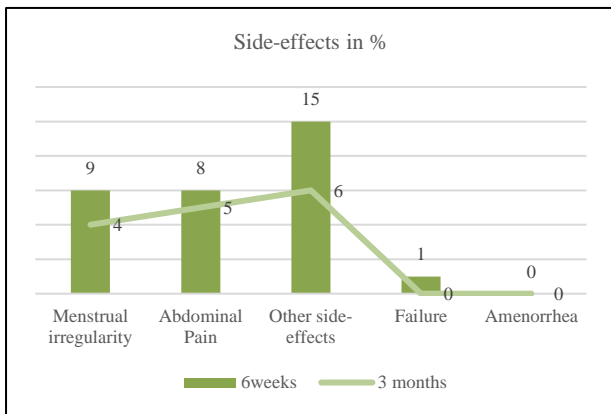
**Figure 5: Client characteristics at recruitment.**



**Figure 6: Contraceptive used in the past.**

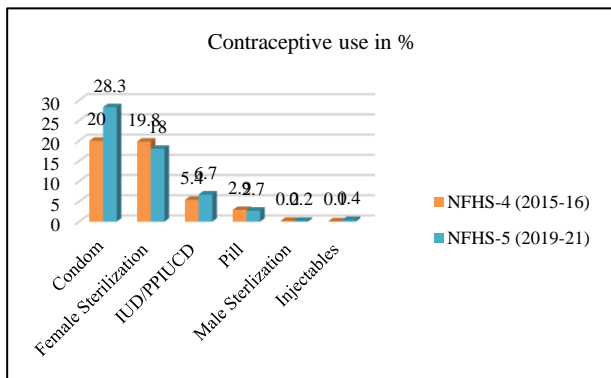


**Figure 7: Follow up details of clients on centchroman.**



**Figure 8: Side effects associated with centchroman at 3 months of use.**

Other side-effects: abdominal pain, weight gain, gastritis, body ache, back pain and vaginal discharge.



**Figure 9: Utilization of contraceptives in India from 2015-21.**

## DISCUSSION

There was a dramatic utilisation of centchroman from 0.5-0.7% to 29% at the end of the study. Key findings of this study indicate that the inclusion of the key stakeholders for family welfare programmes is very important for the successful utilization of services. The challenges to be faced at each level of implementation varies with

countries, culture and even with states and territories within a country. It is important to address sensitization and capacity building at each level of service: in this study the important people were the healthcare providers including the field workers (ASHA), clients and their families. The policies need to be customized to the needs of the key players. This study highlights simple yet effective steps which could bring a change regarding the utilisation of a contraceptive which is permitted for use early in postpartum period. This has the advantage of higher uptake among the users. The implications are important in low resource countries.

Cleland et al, in their study reported that family planning can avert the 32% of maternal deaths and 10% of childhood deaths.<sup>6</sup> Expansion and introduction of new methods to the basket of contraceptive methods are expected to have a positive impact on contraceptive use.

Centchroman acts as a selective oestrogen receptor modulator with tissue selective oestrogenic or antiestrogenic effects.<sup>7</sup> It suppresses the oestrogen receptors in the reproductive organs but stimulates those of other organs like the bones.<sup>7</sup> It is used as a contraceptive pill and also prescribed in treatment of abnormal uterine bleeding, mastalgia and fibroadenoma due to its oestrogen antagonist effect.<sup>9</sup> Since 1992, it has been available on the Indian market, but in 2016, the government added it to the free distribution scheme. Initial small studies of this non-steroidal contraceptive demonstrated good therapeutic index and acceptable pregnancy protection.<sup>7,9</sup> However, well powered large randomized controlled trials are currently not available. A scoping review identified eight studies reporting the effectiveness of centchroman as a weekly contraceptive pill involving a total of 2544 women. The reported effectiveness ranged from 96% to 98% in clinical trials and 93% to 100% in observational studies.<sup>10</sup> This is slightly lower than the Indian national guidelines.<sup>11</sup> Continuous bleeding and prolonged cycles >45 days were the two most reported side effects among centchroman users.<sup>10</sup> Contraceptive failure occurred in one woman in our study. The pearl index in our study was 0.43/HWY which is much lower than other Indian studies (2.0-4.2/HWY).<sup>12,13</sup>

The major menstrual complaint was delayed menstrual cycles seen in 15.06% of the acceptors in our study which is higher comparing the 8% in literature.<sup>9,7</sup> In the study by Doke et al, amenorrhoea was seen in 4.11% women in postpartum group while the occasional systemic side effects included headache and vomiting which were comparable with the normal incidence in general population.<sup>14</sup> The systemic effects observed in our study were abdominal pain, gastritis and weight gain (Figure 8). These were important reasons for discontinuation of the pill. However, it is an important counselling point that majority of the symptoms resolved at 3 months of use.

Postpartum women are eager to learn about contraception. In our study, we found that counselling and imparting

contraception instruction is easier when the patient is accompanied by a family member.

To maintain a buffer stock, the supply chain for the pills was closely monitored. As a result, centchroman pills for a period of 3 months was handed over to the parturient women upon discharge from the hospital.

India country statistics of past 6 years indicate that the utilization of oral contraceptive pills (the steroidal contraceptives) is quite low compared to IUCDs and ligation (Figure 9).<sup>15</sup> Since it is non-steroidal pill, centchroman, has potential for wider use. However, it is yet to find its place. Simple steps for problem identification and practical remedial measures can provide long term solutions as has been demonstrated by the present study.

Quality improvement team members faced a challenge in convincing care givers to prescribe this contraceptive. Centchroman doesn't appear on the list of contraceptives and medical eligibility criteria used by most family planning clinics. There is therefore a lack of familiarity with its use. Newly inducted medical personnel should receive regular sensitization training. Until now, no QI initiative has been conducted on this subject based on a literature search.

The strength of the study includes participation of all the stakeholders involved to bring a positive change in the utilisation of the contraceptive through simple interventions which modified the process of care and ensured easy availability of the contraceptive and not requiring additional equipment or financial inputs. The methodology used for quality improvement in the study can easily be replicated in other facilities and for similar challenges.

The limitation includes a large number of clients who were lost to follow up. One important identifiable reason was the COVID pandemic which resulted in the break in regular supply of the contraceptive and restricted travel to the healthcare facility to get the supply.

### Challenges

Convincing the care givers about the use of this contraceptive was an important challenge faced by the quality improvement team. This contraceptive does not figure in the WHO list of contraceptives and medical eligibility criteria which is most often used in the family planning clinic. Therefore, there is lack of familiarity with its use. It is important to hold regular sensitization trainings specially for the newly inducted medical personnel. This was a novel project, and a literature search has failed to reveal any QI initiative on this subject until. In institutions with a high unmet need for contraception, especially in the postpartum period, replication of the interventions suggested in this project may be beneficial.

## CONCLUSION

As a result of the quality improvement initiatives, centchroman utilization increased to 29% from 0.5%, which is much above the national average. No additional infrastructure or financial support was required for any of the interventions in the project. To ensure that this improvement continues, the authors admit that continuous monitoring is needed. The project team will continue to follow monthly statistics to identify deviations and address them proactively. The therapeutic efficacy of centchroman is good, and its side effects are manageable. Centchroman plays an important role in postpartum contraception because of its safety profile in breastfeeding women. If women are provided with guidance and follow-up messages in an easy-to-understand language at every stage of their reproductive cycle, the use of contraception pills can be improved in India.

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*Conflict of interest: None declared*

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

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