Combined hormonal versus nonhormonal versus progestin-only contraception in lactation

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An updated version of this systematic review has been published and can be found online at [www.cochrane.org](http://www.cochrane.org). We will soon update the below RHL summary to reflect the updated findings of the systematic review.

Contraceptive choices for lactating women may be limited due to concerns about effects steroidal hormones. Ideally, the contraceptive method chosen should not interfere with lactation. Additionally, because the return of menstruation and ovulation can be unpredictable in breastfeeding women, the timing of contraception initiation is important.

**RHL Commentary by Levy DP**

1. EVIDENCE SUMMARY

This review analysed data from 5 trials that compared: (i) combined hormonal with progesterone-only contraceptive pills (1 WHO trial conducted in Hungary and Thailand); (ii) combined hormonal contraception with a placebo (2 trials, conducted in the USA and Germany); (iii) progestin-only pill with a placebo (1 trial conducted in Mexico); and (iv) 2 different initiation timings for the progestin-only pill (1 trial from Kenya). Overall, the methodological quality of all included trials was poor. Sample sizes ranged from 20 to 200 women, and for 3 trials the trial duration was especially short (10–21 days). Finally, loss to follow-up was higher than 30% in the 2 larger trials (sample sizes 171 and 200), which seriously undermined the trial validity. As indicated by the reviewers, milk volume measurements might not have been optimal in the trials, and women were not always fully breastfeeding, with supplemental foods to infants being potential confounders. The reviewers' conclusions are straightforward: evidence from the well-conducted trials is inadequate to make recommendations regarding hormonal contraceptive use in lactating women and to establish an effect of hormonal contraception on milk volume or quality. No obvious adverse effect of hormonal contraceptives on infant growth has been documented. Given the limited data available, decisions about type and timing of hormonal contraception in postpartum lactating women should be made on other grounds.

Methodologically, the review is sound. Only randomized trials were included and the data were extracted and analysed appropriately. Outcome measures were reasonably chosen (namely, contraceptive efficacy, milk volume and composition, duration of lactation and infant growth). Among the 50 potentially eligible
trials, only 5 met the inclusion criteria (standard Cochrane criteria, including quality of randomization, allocation concealment, blinding and analysis). Most of the studies initially selected were excluded because they had not been properly randomized. It is not clear from the review whether the reviewers actually searched the literature for language versions other than English, such as Chinese, since no Chinese language trials were cited as having been excluded.

Despite the rigor of its methodology, the lack of good-quality studies limits the significance of the review's conclusions.

2. RELEVANCE TO UNDER-RESOURCED SETTINGS

2.1. Magnitude of the problem

Since the year 2000, some 18 million women have delivered in China every year. Among them, 70%–95% exclusively breastfeed for a mean period of 3–24 weeks, depending on the area (the average total duration of breastfeeding was 5 months in most of the studies conducted in Shanghai before 1995) (1, 2). In urban areas in China, supplemental foods are often added within the first months postpartum, making lactational amenorrhea (LAM) for contraception a less reliable choice than in other developing countries (3). Moreover, the total duration of breastfeeding has decreased in urban areas in recent years.

Between 10% and over 60% of women in China do not use an effective contraceptive method at the time of first intercourse post partum, and more than 80% of Chinese women say they do not need a contraceptive at 3 months post partum (4, 5). The main contraceptive methods used at that time are LAM, the condom, and the intrauterine device (IUD). Less than 20% of women have an IUD inserted during the first year post partum, and in more than one-third of the cases IUD insertion occurs after an induced abortion (5).

A study conducted in Shanghai between 1987 and 1995 reported contraceptive use before and after marriage for 7,336 couples (4). More than 4 couples out of 10 reported at least one pregnancy after the first birth, which occurred mainly during the first 2 years post partum; the vast majority of these pregnancies were terminated. Abortion rates were high in the first 2 years post partum (16.4 per 100 couple-years), and stabilized around 4.8 per 100 couple-years thereafter. Forty per cent of the intercourse episodes were unprotected during the 1st year post partum. Contraceptive prevalence rose to 94% and 96% during the second and third years post partum, respectively.

2.2. Applicability of results

The findings of the review are inconclusive regarding the effect of hormonal contraceptives during lactation. Assessing the applicability of the results is not relevant when the evidence base is so weak.

2.3. Implementation of the intervention

Owing to inconclusive findings, the review does not describe or recommend an intervention as such. The authors’ objective was to evaluate the possible adverse consequences of hormonal contraceptive methods on breastfeeding duration and quality. In the absence of reliable evidence, under-resourced countries are left with the currently existing guidelines. In China, the recommendations of the World Health Organization and those of the Ministry of Health are in use.

The effectiveness of pre- or postpartum education about contraceptive use has not been evaluated adequately (8). Although there is some indication of short-term benefit in terms of contraceptive use, no data are available from randomized controlled trials to demonstrate that such education has an impact on unplanned pregnancies. In fact, it is not known whether postpartum women are motivated to use contraception and whether they are open to educational discourses in immediate postpartum period. In addition, surveys conducted post partum indicate that women may wish to discuss contraception prior to delivery and/or after
hospital discharge, preferably in the context of general education about maternal and child health (12). In China, both the mother and her newborn automatically have an appointment with a health professional at 42 days post partum. This could indeed be a proper time for advising women regarding postpartum contraceptive use.

Since 2003, the guidelines issued by the Chinese Ministry of Health recommend IUD insertion at that time for women who have delivered vaginally. However, more than 50% of women in urban China are currently having Caesarean sections, precluding early IUD insertion. For these women, condoms, implants and vaginal rings should be considered.

3. RESEARCH

Future research should address the following four issues:

- Randomized comparison of immediate versus delayed postpartum IUD insertion in terms of expulsion rates, bleeding patterns, and acceptability for women as well as for health professionals in China.
- Barriers to progestin-only methods use for postpartum contraception in Chinese women and couples.
- Postpartum education on contraceptive use, including LAM, should be evaluated using randomized controlled trials for its effectiveness, particularly in terms of unplanned pregnancies, contraceptive use and knowledge, and breastfeeding practices. Postpartum delivery of contraceptive education should be compared with other patterns of delivery such as antepartum family planning education, and the integration of family planning services with mother and child health services. It may also be important to explore the role of social context in modifying the potential effectiveness of postpartum education on contraceptive use.
- Very little is known about safety of emergency contraceptives (levonorgestrel as well as mifepristone) in lactating women, particularly, progestin concentrations in breast-milk after levonorgestrel use. Research should focus on whether women should stop breastfeeding, and for how long, after the use of emergency contraceptives.

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