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#### FPIN'S CLINICAL INQUIRIES

### Combined Oral Contraceptives for Mothers Who Are Breastfeeding

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#### Clinical Question

Is breastfeeding safe for infants if their mothers use combined oral contraceptives?

#### **Evidence-Based Answer**

There is currently no evidence of harm; however, few patients have been studied and existing studies have many limitations. Therefore, it is not possible to definitively answer this question at this time. The existing low-quality evidence suggests that combined oral contraceptives may reduce the volume of breast milk but not affect the growth of infants. [Strength of Recommendation: B, based on inconsistent or limited-quality patient-oriented evidence]

#### Evidence Summary

Combined oral contraceptives are more effective, more familiar to most patients, and do not have to be taken on as strict a schedule as progestin-only pills; however, concern remains about their safety for infants of mothers who are taking combined oral contraceptives while breastfeeding. A Cochrane systematic review<sup>1</sup> on the subject included three trials with 371 patients that compared the effects of combined oral contraceptives with a control. The studies were of limited quality because they did not specify how the subjects were randomized; the loss-to-follow-up rates were high, not reported, or unclear; no sample size calculation was performed in two of the trials; and the method of allocation concealment was not reported in two of the trials.

Two of the trials,<sup>2,3</sup> published in 1966 and 1970, compared the effects of combined oral contraceptives with placebo and reported conflicting evidence; one study<sup>2</sup> reported inhibitory effects on milk volume and duration of lactation. The other study<sup>3</sup> found no differences in milk volume, lactation initiation, or infant growth. The outcomes were not well quantified in either study, making it difficult to interpret the data. Further, these two studies<sup>2,3</sup> used combined oral contraceptives containing high doses of estrogen (from 75 to 80 mcg) that are no longer used.

The third trial reported in the Cochrane review compared combined oral contraceptives with progestin-only contraceptives. It found statistically significant declines in milk volume in the combined oral contraceptive group but no significant differences in infant growth or milk composition. Breast milk volume was quantified by pump expression using limited measurements. Despite the fact that this was the largest and most recent of the three studies in the Cochrane review (it included 171 women and was published in 1984), the data should be interpreted with caution because the loss-to-follow-up rate was greater than 30 percent in both groups. In addition, most of the participants in the trials were using supplemental feedings by the 12th week postpartum; these could have masked any detrimental effect the combined oral contraceptives had on infant growth. The Cochrane reviewers concluded that the evidence from the existing randomized controlled trials was inadequate to make recommendations regarding the effects of hormonal contraceptives in lactation.

#### Recommendations from Others

The American College of Obstetricians and Gynecologists recommends that combined oral contraceptives should not be initiated before six weeks postpartum, and then only when lactation is well established and the infant's nutritional status is well monitored. The World Health Organization (WHO) recommends against using low-dose combined oral contraceptives in the first six weeks postpartum for breastfeeding women. The WHO also does not recommend prescribing combined oral contraceptives from six weeks to six months postpartum unless other more appropriate methods are not available or not acceptable. After six months postpartum, use of low-dose combined oral contraceptives was generally recommended. The La Leche League International, an advocacy group for breastfeeding, recommends avoiding combined oral contraceptives in breastfeeding women because of the other choices available. The Physicians' Desk Reference advises that a nursing mother should not use oral contraceptives but should use other forms of contraception until she has completely weaned her infant.

# Clinical Commentary

If combined oral contraceptives are considered after two weeks postpartum (they are relatively contraindicated any earlier because of the risk for thromboembolism), mothers who are breastfeeding and their physicians should be aware of the potential decrease in breast milk volume, the need to monitor the infant's growth, and the alternative forms of available contraception. Abstinence, barrier methods such as condoms, and progesterone-only contraception such as depomedroxy-progesterone acetate (Depo-Provera) are possible choices immediately postpartum.

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